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PRINCIPAL INVESTIGATOR: Mary B. Daly, M.D., Ph.D.

CONTRACTING ORGANIZATION: Fox Chase Cancer Center  
Philadelphia, PA 19111

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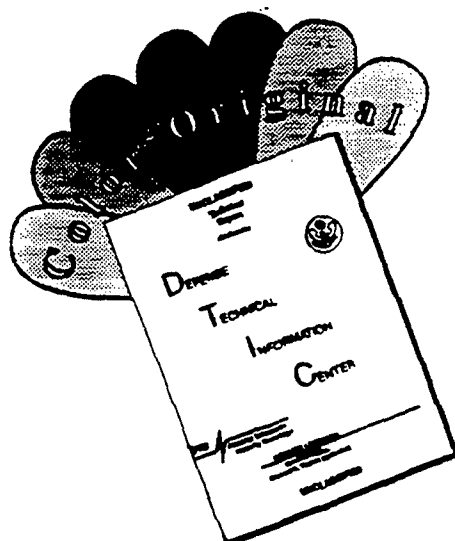
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## Table of Contents

	Page No.
Introduction.....	1
A. Nature of Problem .....	1
B. Background of Previous Work.....	2
C. Purpose of the Present Work.....	4
D. Methods of the Approach .....	5
Figure 1 .....	6
Body .....	7
A. Work of the Risk Advisory Panel.....	8
B. Ongoing Implementation and Accural .....	8
Table I .....	9
Figure 2 .....	10
C. Training .....	10
Conclusions.....	12
References .....	14
Personnel List .....	16
Appendices - contents .....	17
Appendix A.	
Appendix B.	
Appendix C.	
Appendix D.	
Appendix E.	
Appendix F.	
Appendix G .	

## Introduction

### A. Nature of the Problem

The Human Genome Project is an international effort jointly funded by the National Institutes of Health (NIH) and the Department of Energy (DOE) to map the entire human genome and a series of model organisms. Over the next ten years the project has the potential to describe the 4000 genes thought to be responsible for human genetic disease (1). By providing highly sophisticated molecular tools to diagnose genetic susceptibility to cancer, the knowledge gained by the Human Genome Project will have major public health implications in terms of genetic screening policies, patient education, counseling strategies, and health care policy.

The clinical implications of the findings of the Human Genome Project are already becoming evident. Mutations in the BRCA1 gene on chromosome 17q are thought to account for the majority of hereditary breast and ovarian cancers (2). A second breast cancer susceptibility gene, BRCA2, has recently been localized to chromosome 13 and appears to account for a significant proportion of hereditary male and female breast cancer (3). At least four genes associated with hereditary non-polyposis colon cancer (HNPCC) are described and are associated with a broad range of gastrointestinal and genitourinary cancers (4). Altogether, over 12 genetic-cancer syndromes have been localized to a specific gene (5).

Some families suffer from an extraordinarily high incidence of breast and ovarian cancers. It has been estimated that 5 to 10% of cases may be due to inherited predisposition, but the exact number and distribution of predisposing genes is unknown. The existence of these families has prompted an intense search for the genes which predispose individuals to these cancers, as well as the far more common sporadic forms of these diseases. Building on the results of linkage studies (6,7), investigators have recently identified a breast and ovarian susceptibility gene, referred to as BRCA1 (2). Germ-line mutations in BRCA1 account for cancer susceptibility in 40 to 50% of female breast cancer families and more than 80% of breast-ovarian cancer families (8,9). It is estimated that between one in 300 to one in 800 people in the general population possess an altered copy of BRCA1 and that these heterozygous carriers have a resulting 85% and 63% lifetime risk of developing breast cancer or ovarian cancer, respectively (10).

Of the more than 100 unique germ-line mutations detected in the breast and ovarian cancer susceptibility gene (BRCA1), the two most common alteration are a two base pair deletion found at base 185 in exon 2 and a one base insertion at base 5382 in exon 20 (11,12,13,14). These mutations have been detected primarily in individuals of Jewish Ashkenazi descent (11,15,16). Of the 13 to 14 million Jews alive today, 80% are Ashkenazim (13). Data from epidemiological studies of Idiopathic Torsion Distonia suggest that a small founder population from the "Jewish Pale of Settlement" (historically the western part of Lithuania, Poland, and Byelorussia) may have given rise to the existing Jewish Ashkenazi population (18). Data from Tay-Sachs and cystic fibrosis screening studies indicate that approximately one percent of all Ashkenazi Jews may carry the 185delAG mutation (19). Thus the potential impact world-wide of this mutation as well as the 5382insC and other mutations yet to be identified in the Jewish Ashkenazi population is great. Work at the Fox Chase Cancer Center (FCCC) has recently identified a third BRCA1 mutation in several Ashkenazi Jewish kindred with a high incidence of breast cancer. All of this information suggests that the BRCA1 mutation may be amplified within the Jewish Ashkenazi population and further research needs to be done to characterize BRCA1 mutations, its prevalence in this population, whether certain segments of this population share an excessive risk, and implications for genetic testing.

The excitement generated by recent advances in cancer genetics has led to an increased awareness among the public of the risk associated with a family history of cancer. As individuals are becoming more aware of the risks associated with familial cancer and of the complex series of issues such a risk provokes, they are seeking more information and active involvement in efforts to reduce their risk. We and others have documented a significant interest in genetic testing among high risk populations, with as many as 85% of women with a family history of breast cancer indicating that they would seek genetic testing when available (20, 21). As genetic testing for hereditary cancers becomes clinically available, it will be particularly important to optimally prepare individuals for the receipt of genetic risk information and for making the choice of participating in genetic testing a truly informed decision. Already, genetic services for the evaluation of familial cancers are being implemented at a number of comprehensive cancer centers. Based on the model of traditional reproductive genetic counseling, these programs include education about the contribution of heredity to cancer risk, evaluation of personal risk status, and guidance in health decisions. While these sophisticated programs are providing the models for future cancer prevention, they serve only a fraction of the at-risk population, and are often segregated from the mainstream of medical care. Genetic testing services available from commercial laboratories will instead rely largely on the primary care physician to assume the roles of risk identification and counseling. The true preventive potential of a genetic approach to cancer prevention cannot be realized until comprehensive models of risk education and counseling are introduced and incorporated into the primary delivery of health services.

Coincident with the rapid progress in understanding the genetic basis of cancer, the current health care reform movement is seeking to control the escalation of medical costs, and has placed an emphasis on a more generalized approach to care. These efforts are promoting a shift in clinical research for both new treatment modalities and health promotion from the specialized centers of learning to the community providers of care. Accompanying this movement is a growing appreciation of the role of the primary care practitioner in efficiently applying new biomedical knowledge and novel therapeutic strategies to improve the health of the population. Further support for the active involvement of primary care providers in cancer control is found in the emphasis accorded to preventive medicine in family practice training programs (22).

A large computerized data base which includes both genetic and environmental risk information from a racially and ethnically diverse set of patients with familial breast cancer, and from women at increased risk for the disease due to a positive family history, will allow investigators from a wide range of disciplines to address questions of gene-environment interactions, of the relative role of reproductive events in women with a genetic risk for breast cancer, and of the underlying reasons for differences in morbidity and mortality from breast cancer in different age and racial groups. It will further our understanding of the genetic basis of breast cancer by identifying families appropriate for genetic studies. The opportunity to maintain long-term follow-up of the women enrolled in the registry will permit evaluation of the effectiveness of new surveillance and prevention strategies. Moreover, preparing community providers to identify and counsel women at high risk for breast cancer will serve as a model for transferring genetic information into the public health realm.

#### B. Background of Previous Work

The Family Risk Assessment Program (FRAP) was established at FCCC in 1991 by Dr. Daly to meet several needs: 1) to offer to breast cancer patients and their family members education and information about cancer risk, screening, diagnosis, and treatment; 2) to serve as a research base for ongoing evaluation of the epidemiologic, biologic, genetic and environmental lifestyle factors which influence breast cancer risk; 3) to develop predictive models which will incorporate pedigree data, linkage analysis information and epidemiologic



risk factors to more precisely estimate cancer risk; and 4) to develop models for the communication of breast cancer risk information.

Candidates for FRAP include women with one or more first degree relative with breast and/or ovarian cancer. They are identified through their affected relatives, or are self-referred or referred by their primary care physicians for cancer risk counseling. Since the inception of the program a total of 870 high risk women have become participants in the program. Their ages range from 21 years to 75 years, with a median of 40 years. The majority (97%) of the participants are Caucasian, while 3% are African American, Hispanic, or Asian.

On the basis of data provided by each participant on both family history and other pertinent risk factors, an individualized risk estimate for breast cancer is calculated. Trained counselors consider not only the occurrence of cancer within the family, but also the patterns of occurrence and the ages of the affected individuals in determining the type of familial pattern observed. Approximately 40% of FRAP participants meet the criteria for putative hereditary breast/ovarian cancer (i.e. three or more affected relatives in two or more generations) (23), and are eligible for genetic testing protocols. Genetic testing is done in collaboration with Dr. Andrew Godwin.

To date, we have collected blood samples from over 300 families participating in the FRAP and 12 families in the DOD High Risk Registry.

Evaluation of some of the high risk cancer families accrued for mutation in a number of cancer susceptibility genes (i.e. BRCA1, BRCA2, TP53, and CDKN2) has uncovered mutations in the BRCA1 gene in 48 families followed at FCCC. Within these families, we have been able to identify nearly 100 BRCA1 mutant allele carriers, more than half of whom are currently asymptomatic. In a recent study, 163 women from breast-ovarian cancer prone families and 178 individuals affected with breast and/or ovarian cancer but unselected for family history for germ-line mutations in exon 2 of BRCA1 were screened. A total of twenty-five mutations were detected. Thirteen of sixty-four Jewish Ashkenazi women and two non-Jewish individuals were found to possess the 185delAG mutation. Haplotype data for all individuals using markers intragenic to BRCA1 suggest that the Jewish Ashkenazi individuals share a common ancestry that is distinct from the lineage shared by the other two women. These data provided the first evidence of two distinct lines of transmission for the 185delAG mutation, only one of which has its origins in the Jewish Ashkenazi population. This screening also uncovered ten affected individuals with an 11 base pair deletion at nucleotide 188 of BRCA1 (188del11), four of whom are Ashkenazi Jews. This is only the third reported BRCA1 mutation detected within the Jewish Ashkenazi population and may represent the second most common alteration in BRCA1 found in Ashkenazi Jews in the United States (11). Current studies are underway in which more than 200 Jewish women affected with breast and/or ovarian cancer from high-risk families are being evaluated for the 188del11 mutation.

FCCC has recently begun evaluating families for mutations in the BRCA2 gene. Nine families (two males with breast cancer, four females with breast cancer, and three females with ovarian cancer) carrying the same BRCA2 mutation have been identified (24,25). The age of cancer onset in the mutant allele carriers was highly variable: breast cancers were diagnosed between 41 to 72 years of age, while the ovarian cancers were discovered between 48 to 73 years. Evaluation of family histories for the nine mutant allele carriers found that all but one had at least one additional relative affected with breast cancer. Several individuals had significant cancer histories that included, in addition to breast and/or ovarian cancer, an increased incidence of colon, pancreatic, stomach, and hematopoietic cancers. Interestingly, 8 of the 9 individuals were of Ashkenazi Jewish descent. Haplotype data for these 8 mutant allele carriers using markers spanning the region of the BRCA2 gene on chromosome 13q12-

q13 suggest that two of the confirmed Jewish Askenazi individuals share a single common ancestry. Furthermore, haplotype analysis of the non-Jewish individual suggested several independent origins for this BRCA2 mutation. These data provide evidence for the presence of a specific BRCA2 mutation which has its origins in both Jewish Ashkenazi and non-Jewish populations. Overall, of the 24 Jewish individuals with significant breast and/or ovarian cancer histories, five who did not possess the 185delAG, 188del1, or 5382insC BRCA1 mutations, were carriers of a BRCA2 6174delT mutation (25). The observed overrepresentation of specific mutations within a sub-group of the general population may eventually help contribute to the development of inexpensive and routine tests for BRCA1 and BRCA2 (25,26).

#### The Transfer of Cancer Control Strategies to the Community

Fox Chase has also been a leader in extending state-of-the-art cancer knowledge, therapeutics and prevention to health care professionals and to the community. With a long tradition of professional education, including pre- and post-doctoral programs, oncology training at the nursing, medical student, resident and fellow level, and continuing medical education for health care providers, Fox Chase recognizes its responsibility to also disseminate its expertise in cancer prevention and control to the community, as reflected in its many provider outreach efforts. The Community and Physician Awareness Program targets primary care practitioners and members of the community to make them aware of the FCCC-affiliated cancer programs in their communities, and the range of cancer services available to them. Through the Physicians Services Program, physicians in the tri-state area are visited by a physicians' services coordinator who, using an academic detailing approach, provides information about current protocols and clinical programs, including prevention and control initiatives, which are available at the Center. A three year Cancer Education Outreach Program to develop, implement and evaluate an educational program consisting of a series of cancer control education forums for primary care providers who treat underserved populations, and community leaders who serve these populations, has recently been launched. In addition to increasing the knowledge and practice of specific cancer prevention and control protocols, another aim of the program is to enhance the ability of collaborating organizations to provide cancer prevention and control education to their community professionals.

Providing an overarching community framework to all of these outreach efforts is the Fox Chase Network, a unique cooperative relationship between FCCC and 18 community hospitals in Pennsylvania and New Jersey which was established in 1986 with a mission to enhance the quality of cancer care in the community. With assistance from Fox Chase, the Network hospitals have built or expanded existing radiotherapy facilities, improved their inpatient and outpatient oncology units, coordinated community outreach programs, and provided educational programs for their physicians, support staff, and the lay community. Through Fox Chase, the Network hospitals actively accrue patients to the major collaborative group clinical trials, including the two large nationwide chemoprevention trials for breast and prostate cancer.

#### C. Purpose of the Present Work

The establishment of a registry of high risk families is an ideal way to further our understanding of the mechanisms of breast carcinogenesis, and to learn the best ways to provide information and counsel both to women at increased risk for breast cancer and to their primary care practitioners. A large computerized data base which includes both genetic and environmental risk information from a racially and ethnically diverse population will allow investigators to address questions of gene-environment interactions, of the relative role of reproductive events in women with a genetic risk for breast cancer, and of the underlying reasons for differences in morbidity and mortality from breast cancer in different age and racial groups. It will further our understanding of the genetic basis of breast cancer by identifying

families appropriate for linkage analysis studies. The inclusion of a High Risk Specimen Bank in the design of this registry will allow investigators to identify and quantify early premalignant markers of breast cancer risk and to estimate the true prevalence of breast cancer gene(s) in the population. Despite widespread public interest in breast cancer, many first degree relatives of breast cancer patients know very little about their true risk status. The establishment of this registry will give us the opportunity to test different counseling strategies so that we can best meet the needs and demands for information which will accompany the eventual identification of breast cancer susceptibility genes. Long-term follow-up of women enrolled in the registry will permit evaluation of the effectiveness of surveillance and prevention strategies. Finally this registry will serve as a catalyst for the development of educational materials directed towards community-based health care professionals. In the past, genetics counseling has been the exclusive domain of medical geneticists and medical genetics counselors. However, to be successful, the transfer of information generated by the Human Genome Project to the public health realm of cancer control must be put in the hands of the primary care practitioner, both physician and nurse. Essential to the successful development of a community-base Breast Cancer Risk Registry is the ability of primary care practitioners to target breast cancer screening and prophylaxis towards truly high risk individuals, and the dissemination of genetic information back to the primary health care team in the community. The educational tools developed to complement the establishment of a high risk registry will serve as a model for bringing primary care practitioners to the forefront of cancer control and prevention.

#### D. Methods of the Approach

The methods of accomplishing the proposed goals were set out in the grant proposal in eight specific aims (see Figure 1.) The first step proposed was the establishment of a Breast Cancer Risk Advisory Board representing health care professionals, both at FCCC and the Fox Chase Network, community representatives, as well as lay consumers. This group has the mandate to provide information, counsel and advice to the staff of the Breast Cancer Risk Registry (Aim #8). The approach to the work is an annual meeting by the entire panel of experts. The panel identifies pertinent issues that are addressed by subcommittees that meet on an ad hoc basis. The panel's work is helping to guide the research process of establishing and monitoring the Risk Registry and addressing the legal, social and ethical implications of the new genetic knowledge emerging from the Human Genome Project.

**Figure 1. Specific Aims of the Breast Cancer Risk Registry**

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1. To establish a protocol for identifying and recruiting women with one or more first degree relatives with breast cancer into a regional FCCC Network-wide registry of high risk individuals.
  2. To establish a computerized data base system of comprehensive information including family history, personal medical history, lifestyle and environmental factors, health practices and beliefs, and psychological status which will serve as a resource for a spectrum of research activities.
  3. To develop protocols for the selection of individuals and families for closer genetic investigation and genetic counseling.
  4. To expand the FCCC/Network Breast Cancer Tissue Registry to include specimens of benign breast lesions as well as serum and DNA from women in the high risk registry.
  5. To develop educational tools for primary care physicians at the community level to prepare them to take a leading role in the identification of women with a family history of breast cancer, in the interpretation of genetic test data, and in its relevance and application to clinical medicine.
  6. To develop workshops for training nurses at the community level to provide breast cancer risk information, risk assessment, tailored preventive recommendations, and psychosocial support to high risk women and their families.
  7. To develop and test behavioral interventions which are sensitive to cultural, ethnic and racial differences which will promote positive outcomes to breast cancer risk information, including the results of genetic testing.
  8. To form a Breast Cancer Risk Advisory Panel to provide guidance and counsel regarding the social, legal and ethical aspects of genetic testing for breast cancer.
- 

Interaction with the Network hospitals began with the development of a plan of recruitment for first degree relatives of women with breast cancer in collaboration with the Medical Director of each Network Oncology Program. During the second year of the program accrual of high risk women continued. Methods for the accrual into the registry included the completion of a Health History Questionnaire (HHQ) (**Appendix A, See Recruitment Procedures**), and having attended an education session on breast cancer risk. Data from the HHQ were entered into the Risk Registry and family pedigrees were developed. Each pedigree is reviewed by a multidisciplinary team for assignment of family risk selection of families for closer genetic investigation began. (Aims #1 and #3).

The data management system for the FCCC Family Risk Assessment Program, which uses the relational data base product Oracle as the primary software platform for data entry and validation, storage, retrieval, modification, and security, has been utilized for the Network system. The expansion of this data system to a Network-wide Breast Cancer Risk Registry, in addition to maintaining all data in an accurate and consistent fashion, has accommodated the distribution of mailed follow-up questionnaires, and generate appropriate introduction letters for collection of medical records, blood and tissue samples. It has also generated multigenerational pedigrees summarizing the family history, for use both as an educational tool and also to identify those families appropriate for more intensive genetic investigation (Aim #2).

Essential to the success of the Registry has been the development of programs to train both nurses and physicians at each Network hospital for their expanded role in cancer risk identification and counseling. The education methods for nurses have included a formal three day training and one day practicum and quarterly inservice updates in cancer risk assessment and genetic counseling issues. The methods for physicians included regional updates through the physicians services program, grand rounds and one formal symposium (Aim #5, #6, and #7).

To evaluate training and the impact of the training in nursing practice the following methods were used: (1) pretest/posttest measure of knowledge, (2) subjective evaluation of course objectives for each session and total program, (3) baseline and 6 month follow-up survey to assess self-reported practice and confidence as well as facilitators and barriers to implementing Cancer Risk Counseling (CRC) in community practice.

The pre and posttest measure of knowledge was developed from questions submitted by each lecturer. The 30 item questionnaire corresponded to lecture content (**See Appendix B, Pretest**). The items were summed having a value of 1 to 30. The post session/program evaluation tool (**Appendix C**) included questions rating the session objectives ( "not at all" to "completely met"), the effectiveness of the lecturer, relevance of overall course goal ("not at all" to "completely relevant"), appropriateness for training nurses ("too basic" to "too detailed") and recommendations for future training. The baseline and 6 month follow-up survey (**Appendix D**) was adapted with permission from the Cancer Genetic Counseling Survey developed by Dr. Judy Garber and Katherine Schneider of the Dana Farber Cancer Center. It was originally used with genetic counselors to assess level of practice in cancer risk counseling.

In the evaluation phase, descriptive analysis was used to measure the subjective responses to program objectives. Univariate analysis was conducted to compare pre to posttest measure of knowledge using a Wilcoxon signed rank sum test. Univariate analysis was used to measure change over time from baseline to six months post training on taking cancer family histories, practicing cancer risk counseling and confidence in skills in cancer risk counseling.

(Aim #4) Protocols used at FCCC for the collection, transportation and processing of blood samples for genetic testing have been utilized as the model for the Network Hospitals. Dr. Jose Russo, Director of Experimental Pathology at FCCC, agreed to guide the expansion of a High Risk Breast Specimen Bank. Detailed procedures for the protocols were developed and compiled in a procedures manual to assist Network staff in following the protocols.

Quality control measures established to ensure that OSHA standards for the handling of human biologic materials were followed by all specimen bank and laboratory personnel.

Contact with the medical directors at Network institutions was the method used to initiate planning and implementation. This approach allowed for assessing interest in participation in the program as well as determine training, education and administrative needs. Those institutions interested in participation were guided through an implementation process that included training and preparation of nursing staff to coordinate and conduct the program as well as on-going mentoring and monitoring in cancer risk assessment and counseling.

The work of the FCCC Network Breast Cancer Risk Registry is providing the opportunity to develop and evaluate educational and psychological strategies to optimize breast cancer risk counseling in the community setting. It is also providing important information that will guide future research on the optimal way of delivering breast cancer risk information, and the true impact of counseling programs on participants' risk comprehension, psychological adaptation, and adoption of recommended health practices.

### Body

The overall goal of the second year of the Breast Cancer High Risk Registry was to continue accrual to expand the research base regarding the epidemiologic and biologic knowledge about modifiable causes of breast cancer. Therefore, the tasks for this year were to assess the needs of the project as implementation and accrual continued, to evaluate education and counseling needs of the Network staff and to monitor the programs at each of the

participating institutions. The following describes the process and tasks that were accomplished in Year Two.

#### A. Work of the Risk Advisory Panel

The main goal of the Risk Advisory Panel was to provide guidance and expertise on issues and concerns that could arise with providing familial cancer risk assessment and establishing a registry. Therefore, representatives from multiple disciplines and expertise were gathered for the Breast Cancer Risk Advisory Panel (**Appendix E**). These members included consumers, risk registry participants, experts in the area of oncology nursing, genetics, genetic counseling, medical testing, marketing, psychology, the law, health insurance, primary care, and ethics. The whole panel met for an annual meeting in Year Two and identified three working groups: ethics, primary care, and scientific committees.

The ethics group has met to discuss informed consent issues. Since the process for participation in the risk registry involved an education and counseling process at multiple points, the group recommended a consent process to match the counseling process. Three consent forms were developed (**See Appendix A, Administrative Section**). The first consent form is for the collection of personal and family information for the registry data base. The second consent form is for the collection of blood and tissue to become part of the registry. The third consent form will be for those selected individuals who will have the option to receive genetic test results. This group also has discussed the issues of genetic testing research at a time when BRCA1 and BRCA2 testing is being offered commercially. Recommendations are being prepared that will lead to guidelines for all the Network facilities.

The primary care committee was established to address the issues of implementing cancer risk counseling into community practice. This was in response to the panel's concern regarding medical management and subsequent reimbursement issues associated with assignment of risk status and reception of genetic test results. Most cancer risk counseling and genetic testing will be conducted in specialized facilities. For the most part, follow-up and screening will return to the realm of primary care providers. The panel recommended convening representatives from several managed care organizations to explore reimbursement issues for genetic testing. It was also recommended to explore standards of care for surveillance following assignment of cancer risk or genetic carrier status. The group is identifying representatives from managed care organizations to address these issues. This committee will also be developing a primary care provider survey to assess the needs and interest of primary care providers in the area of cancer risk assessment and counseling.

The scientific committee has convened oncologists, geneticists and epidemiologist to examine the continued needs of significant risk data for the registry. They have made recommendations to add items to the Health History Questionnaire for Year Three. In view of the recent findings regarding potential founder affects in the Ashkenazi Jewish population (**11,12,13,14**), additional questions on ethnicity and country of origin will be added. There will also be expanded questions on reproductive history and exercise.

#### B. Ongoing Implementation and Accrual

Contact with the medical directors at Network institutions allowed for assessing interest in participation in the program as well as determining training, education and administrative needs. Those institutions interested in participation were guided through an implementation process that included training and preparation of nursing staff to coordinate and conduct the program. Once a nursing site coordinator was assigned, administrative and procedural components of the program were addressed. The project manager worked individually with the site coordinator to develop an implementation plan tailored for the

individual Network facility. The components of the plan included: recruitment strategies, marketing, administrative requirements, such as Institutional Review Board approval, educational resources, documentation and security for records, strategies for counseling and for collection of blood samples. To clarify all the steps for implementation, the procedures manual from Year One was expanded to include specific instructions for the above mentioned components (**Appendix A, Procedures Manual**). Additionally, all forms and letters were provided on disc and hard copy to facilitate the necessary adaptation for the individual hospital.

An ongoing monitoring process was also instituted. This process included observation and supervision of the breast cancer risk education session and the individual cancer risk counseling session. Ongoing mentoring and monitoring of the programs are provided by telephone conferencing, site visits, and quarterly inservice education. This process is discussed in the training section.

To date, contact with Medical Directors has been made in all but three Network Institutions. Nursing staff have been trained in twelve facilities; of these, seven have assigned a nurse as the program coordinator. The education and program resources have been provided to seven hospitals. Six sites have begun the breast cancer risk education through community education, and five sites have been accruing participants for the Risk Registry. Three other sites are projecting to begin accrual in the beginning of Year Three. Table 1 outlines the status of the individual Network facilities.

**Table I. Network Participation in the Risk Registry Program**

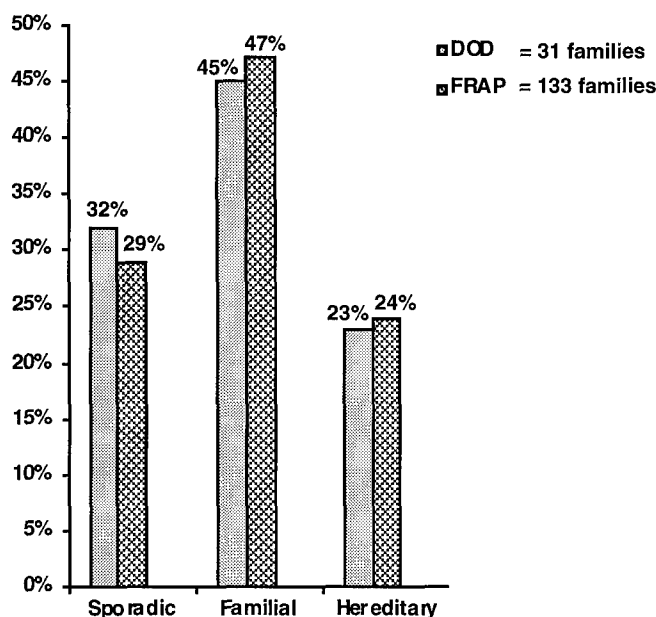
	Contact- Med. Dir	Nurse trained	Nurse coord.	Education resources	Education initiated	Accrual begun
St. Luke's	X	X	X	X	X	
Reading	X	X				
PolyClinic	X	X	X	X		
Burlington (Mem.)	X	X				
St. Francis						
Montgomery	X	X	X	X	X	X
North Penn						
St. Mary's						
Paoli	X	X	X	X	X	X
Riverview	X					
Hunterdon	X	X	X	X	X	X
Delaware County	X	X	X	X	X	X
South Jersey	X	X				
Community Med.	X	X	X	X	X	X

The breast cancer risk education sessions were marketed in two ways: through the medical oncologist contact with breast cancer patients and through community education. In the former, the medical oncologist alerted breast cancer patients about the program. The patients in turn contacted their relatives. Three of the Network hospitals have done general media announcements about the breast cancer education sessions. A description of the Risk Registry Program is given at the education session with the option for participation. During Year Two there were a total of 18 education sessions with 164 women attending. Of those, 54 women from 45 families chose to participate in the Risk Registry program. These women all have had their family history information reviewed by the Pedigree Review Committee at Fox Chase. The purpose of the review is to assign a preliminary diagnosis of the cancer family

pattern, and identify appropriate individuals for further genetic evaluation and collection of blood or tissue samples. Each family receives a diagnosis for both the maternal and paternal side of the family by cancer type and by pattern. The patterns include: sporadic, family or putative hereditary. Family cancer patterns for the 45 families in the Risk Registry have shown 32% sporadic, 45% familial and 23% putative hereditary. Figure 2. shows the breakdown of the cancer family patterns in the High Risk Registry (DOD) as compared to the Family Risk Assessment Program (FRAP) for its first year of accrual. Since hereditary cancer is expected to account for 5 to 10% of breast cancers, these figures show that the risk registry program is appropriately recruiting individuals that carry a higher degree of risk for breast cancer than the general population. These patterns also show that Risk Registry families are similar to that of the FRAP.

**Figure 2.**

## Preliminary Diagnosis of Cancer Family Pattern



Blood samples were collected for 15 families. Protocols used at FCCC for the collection, transportation and processing of blood samples for genetic testing have been utilized as the model for the Network Hospitals. Detailed procedures for the protocols were developed and compiled in a procedures manual to assist Network staff in following the protocols (**Appendix A, See Procedures Section**).

### C. Training

The second year of the Risk Registry program allowed us to continue to extend the program and to begin to prepare community-based providers with the knowledge and the skills to make familial cancer counseling available. Training for Network nursing staff began



in Year One and a second education program provided training for five Network staff. These included four nurses and one genetic counselor.

An evaluation process was designed to assess the effectiveness of training nurses in Cancer Risk Counseling (CRC) and to obtain data regarding the impact of the course on oncology nursing practice. The pre/posttest measures showed that there was statistically significant improvement from pre to posttest knowledge scores ( $P = .0001$ ) using the Wilcoxon signed rank statistic, with a mean pretest score of 58% and mean posttest score of 76%. There was a 95% completion rate of the subjective course evaluation. Course objectives were rated as "completely met" by 80% of the participants with the majority of participants identifying the role playing as most helpful and recommending that more case presentations and role play activities be included in the program. All participants evaluated the content as being "appropriate" for future training and at a level that was neither "too basic" nor "too detailed".

To further test the impact of the course, survey data at baseline ( $n=36$ ) and six month post-training ( $n=32$ ) analyzed individual and group change over time in providing CRC. At baseline, 56% reported taking cancer family histories. Of these, 50% obtained information from first degree relatives only, 35% failed to record age of diagnosis, and 60% failed to inquire about bilaterality of disease. At 6 months, all respondents collected family history from at least 3 generations, and age of onset for cancer; 67% obtained information on recurrence or bilaterality of disease. Pedigree analysis was utilized as the method to assess risk by 59% at 6 months compared to 24% at baseline; 48% reported plans to initiate cancer risk assessment services compared to 33% at baseline; and 25% had referred patients for genetic testing.

At 6 months, a subset of 21 respondents reported practicing CRC compared to 5 at baseline. All respondents who practiced cancer risk counseling skills over the last six months ( $n=21$ ) correctly collected age of onset of cancer and age of death. Family history information was collected on at least three generations by the respondents, and on four generations by 72%. Overall, there was self-reported improvement in counseling skills and confidence in providing cancer risk information.

Respondents indicated that having other trained staff at their institutions was the most important facilitator for implementation of the program and a need for continued training was cited by 22 of the respondents. Furthermore, the majority of the respondents ( $n=28$ ) identified the need for guidelines for nurses in Familial Cancer Risk Counseling.

In March 1996, data from this project were presented in a poster presentation at the American Society of Preventive Oncology (**Appendix F, Bibliography**). In May 1996, a podium presentation at the Oncology Nursing Society Annual Meeting, entitled Familial Cancer Risk Counseling: Development and Evaluation of a Training Program for Nurses, was presented (**Appendix F**).

An ongoing monitoring process was also instituted. This process included observation and supervision by FCCC staff of the breast cancer risk education session and the individual cancer risk counseling session. All Network nurses had the opportunity to observe in the FRAP program. Their observations included attending pedigree review and the individual pedigree evaluation session. Feedback on pedigrees was given prior to each individual session. For the initial individual counseling session at the Network Hospital, the nursing coordinator observed FCCC staff conduct an individual risk assessment session. Afterwards, FCCC staff supervised the nurse coordinator conduct two sessions. Since genetic information has been rapidly expanding, there needed to be a way to provide updates for information as well as individual concerns and issues raised during counseling. A monthly mailing of current literature was established. A quarterly inservice training was also instituted. These four hour

trainings consist of peer updates regarding individual Network hospital progress in the Risk Registry, review of administrative concerns or issues, and two hours of educational inservice. Additional monitoring of the program is provided by telephone conferencing and site visit.

The process of training and preparing nurses to assume the role of providing cancer risk information has underscored the need to bring physicians into the loop of a genetic based approach of cancer prevention. During the Risk Registry Program, the nurse coordinators have the opportunity to obtain information from the research project team. As cancer risk counseling becomes part of community practice, information needs will be better addressed by the practice team. Physicians in the Network hospitals were offered ongoing updates regarding the advances in genetics via the Network's Physician Services. This service organizes regional inservice updates and grand rounds. Cancer risk assessment and genetic updates were presented at two regional meetings and four grand rounds at Network Institutions. Dr. Mary Daly in cooperation with the FCCC Continuing Medical Education Department provided an offering for physicians in the genetic advances in cancer control. (**Appendix G, Toward 2000 brochure**). This one day symposium addressed cancer genetics and prevention. There was a special workshop on cancer risk assessment. This program was attended by over 100 area physicians as well as those medical directors participating in the Risk Registry Program.

As part of Fox Chase Cancer Center's effort to educate physicians, the needs of practicing physicians regarding the identification of genetic risk for disease and the options available for high risk families became more apparent. Following from the work of the Risk Registry Grant, Fox Chase was awarded funds from National Cancer Institute Award to pilot an education program for family practice residents. The work of this program called: "Training Family Practice Residents in Familial Cancer Risk Counseling", will provide the information necessary to develop feasible and effective educational strategy for the widespread dissemination of information about cancer genetics and its relationship to breast cancer.

### Conclusions

The work of Year Two of the High Risk Registry Program has seen the continued education and accrual of women at high risk for breast cancer. Six Network hospitals have begun the breast cancer risk education through community education, and five sites have been accruing participants for the High Risk Registry Program. Three other Network sites are to begin accrual in the beginning of Year Three. Counseling strategies for conveying risk information based on family cancer patterns has begun. This work of establishing risk assessment services within the community has been guided by the work of the Advisory Panel. The Panel's working committee has offered clarity to the informed consent process as part of the counseling strategy. The issues of primary care practitioners regarding reimbursement and follow-up will also be addressed to make cancer risk counseling a feasible service within the community. The Risk Advisory Panel will continue to guide the dissemination of the High Risk Registry Program into Year Three.

Based on the training needs of the nurses in the program and monitoring the registry activities, it is apparent that ongoing education is still a need in the rapidly changing field of genetics. As more Network Hospitals become part of the registry, creative strategies for providing education and supervision are needed. The project manager along with the training coordinator are developing a series of case presentation via video to simulate counseling sessions. These video vignettes will be used as part of the quarterly inservice training. Additionally, teleconferencing strategies will be tested to enhance the skills of the nurse coordinators in the cancer risk counseling process.

Now that recruitment and collection of blood and tissue samples is underway, efforts will be made to develop counseling interventions for delivery of genetic test results as part of a community based practice. The Fox Chase Team will share protocols for predisclosure and disclosure counseling. Network staff will receive training prior to conducting disclosure sessions. A mentoring process for delivery of test results will also be developed. This next step will increase the number of skilled providers who can appropriately communicate and counsel women regarding genetic information.

## References

1. Rossiter, B.J.F., Caskey, C.T. "The human genome project and clinical medicine," Oncology 61-68, 1992.
2. Miki, Y., Swensen, J., Shattuck-Eidens, P., et al. "A strong candidate for the breast and ovarian cancer susceptibility gene BRCA1," Science 266:66-71, 1994.
3. Wooster, R., Neuhausen, S.L., Mangion, J., et al. "Localization of a breast cancer susceptibility gene, BRCA2, to chromosome 13q12-13," Science 265:2088-2090, 1994.
4. Rhyu, M. "Molecular mechanisms underlying hereditary nonpolyposis colorectal carcinoma," JNCI 88:240-51, 1988.
5. Thompson, J., Wiesner, G., Sellers, T., Vachon, C., Ahrens, M., Potter, J., Sumpmann, M., Kersey, J. "Genetic services for familial cancer patients: A survey of National Cancer Institute Cancer Centers," JNCI 87(19):1446-55, 1995.
6. Hall JM, et al. "Linkage of early-onset familial breast cancer to chromosome 17q21," Science 250:1684-1689, 1990.
7. Narod SA, et al. "Familial breast-ovarian cancer locus on chromosome 17q12-q23," Lancet 338:82-83, 1991.
8. Easton DF, Bishop DT, Ford D, Crockford GP & Consortium, B.C.L. "Genetic linkage analysis in familial breast and ovarian cancer: Results from 214 families," Am J Hum Genet 52:678-701, 1993.
9. Narod SA, et al. "An evaluation of genetic heterogeneity in 145 breast-ovarian cancer families," Am J Hum Genet 56:254-264, 1995.
10. Ford D, et al. "Risks of cancer in BRCA1-mutation carriers," The Lancet 343:692-695, 1994.
11. Berman DB, Costalas J, Schultz DC, Lynch HT, Daly M, Godwin AK "Two distinct origins of a common BRCA1 mutation in breast-ovarian cancer families: a genetic study of fifteen 185delAG mutation kindreds," Am J Hum Genet, 58:1166-1176, 1996.
12. Shattuck-Eidens D, McClure M, Simard J, Labrie F, Narod S, Couch F, Hoskins K, et al. "A collaborative study of 80 mutations in the BRCA1 breast and ovarian cancer susceptibility gene. Implications for presymptomatic testing and screening," JAMA 273:535-541, 1995.
13. Simard J, Tonin P, Durocher F, Morgan K, Rommens J, Gingras S, Samson C, et al. "Common origins of BRCA1 mutations in Canadian breast and ovarian cancer families," Nature Genet 8:392-398, 1994.
14. Struewing JP, Brody LC, Erdos MR, Kase RG, Giambarresi TR, Smith SA, Collins FS, et al. "Detection of eight BRCA1 mutations in 10 breast/ovarian cancer families, including 1 family with male breast cancer." Am J Hum Genet 57:1-7, 1995.

15. Friedman LS, Szabo CI, Ostermeyer EA, Dowd P, Butler L, Park T, Lee MK, et al. "Novel inherited mutations and variable expressivity of BRCA1 alleles, including the founder mutation 185delAG in Ashkenazi Jewish Families," Am J Hum Genet 57:1284-1297, 1995.
16. Tonin P, Serova O, Lenoir G, Lynch TH, Durocher F, Simard J, Morgan K, et al. "BRCA1 mutations in Ashkenazi Jewish women," Am J Hum Genet 57:189, 1995.
17. Dellapergola S. "Major demographic trends of world Jewry: the last hundred years." In: B. Bonne-Tamir and A. Adam, ed. Genetic Diversity Among Jews: Diseases and Markers at the DNA Level Oxford University Press, New York, 3-30, 1992.
18. Risch N, deLeon D, Ozelius L, Kramer P, Almasy L, Singer B, Fahn S, et al. "Genetic analysis of idiopathic torsion dystonia in Ashkenazi Jews and their recent descent from a small founder population," Nature Genet 9:152-159, 1995.
19. Struewing JP, Abeliovich D, Peretz T, Avishai N, Kaback MM, Collins FS, Brody LC "The carrier frequency of the BRCA1 185delAG mutation is approximately 1 percent in Ashkenazi Jewish individuals," Nature Genet 11:198-200, 1995.
20. Lerman, C., Daly, M., Balshem, A. "Attitudes about genetic testing for breast-ovarian cancer susceptibility," Journal of Clinical Oncology 12:843-850, 1994.
21. Croyle, R.T., Lerman, C. "Interest in genetic testing for colon cancer susceptibility: Cognitive and emotional correlates," Preventive Medicine 22:284-292, 1993.
22. Williams, P.T. "The role of family physicians in the management of cancer patients," Journal of Cancer Education 9(2):67-72, 1994.
23. Grana, G., et al. "The significance of a familial cancer risk triage approach on genetic cancer screening policies," (abstract). American Society of Human Genetics 1995.
24. Couch, F.J., Farid, L.M., DeShano, M.L., Tavtigian, S.V., et al. "BRCA2 germline mutations in male breast cancer patients and breast cancer families," Nature Genetics 13:123-125, 1996.
25. Berman, D.B., Costalas, J., Schultz, D.C., Grana, G., Daly, M., Godwin, A.K. "A common mutation in BRCA2 that predisposes to a variety of cancers is found in both Jewish Ashkenazi and non-Jewish individuals," Cancer Research 56:3409-3414, 1996.
26. Tonin, P., Weber, B., Offit, K., Couch, F. "A high frequency of BRCA1 and BRCA2 mutations in 222 Ashkenazi Jewish breast cancer families," Nature Medicine (submitted for publication, 1996).

**Personnel List**  
**Department of Defense Infrastructure Grant**  
**High Risk Registry Program**

Mary Daly, MD, Ph.D.,	Principal Investigator
Agnes Masny, RN, MPH	Project Manager
Josephine Costalas, MSc	Genetics Counselor
Rose Batson	Data Entry
David Berman, MSc	Lab Technician

**Department of Defense Infrastructure Grand  
Breast Cancer High Risk Registry  
September 14, 1995 to September 14, 1996**

**Appendices**

Appendix A	Procedures Manual
Appendix B	Pretest for Nurses' Training
Appendix C	Post Session and Program Evaluation
Appendix D	Baseline and Six Month Follow-Up Survey
Appendix E	Risk Advisory Panel
Appendix F	Bibliography of Abstracts
Appendix G	Toward 2000 Brochure

## **APPENDIX A**



## **Manual Contents**

### **Section 1 - Administrative**

Flow Chart - Assessing Cancer Genetic Risk  
Major Components of Family Risk Assessment Process  
Genetic Cancer Risk Counseling Protocol  
IRB Approval for High Risk Registry/CFRCS  
Disclaimer Notice  
Explanation of Informed Consent Samples  
Information on Fox Chase Breast Cancer Risk Registry  
Informed Consent - ELSI #2  
Informed Consent - ELSI #3

### **Section 2 - Marketing**

Protocol Alert  
Brochure - Draft  
Brochure - Sample Paoli Memorial Hospital

### **Section 3 - Recruitment**

Baseline Survey Contact Log  
Health History Questionnaire  
POMS, MBSS, RIES  
Letter to Confirm Education Session  
Group Education Session  
Health History Instructions  
Interest Sheet  
Screening Letters and Recommendations  
Breast Cancer Screening Recommendations

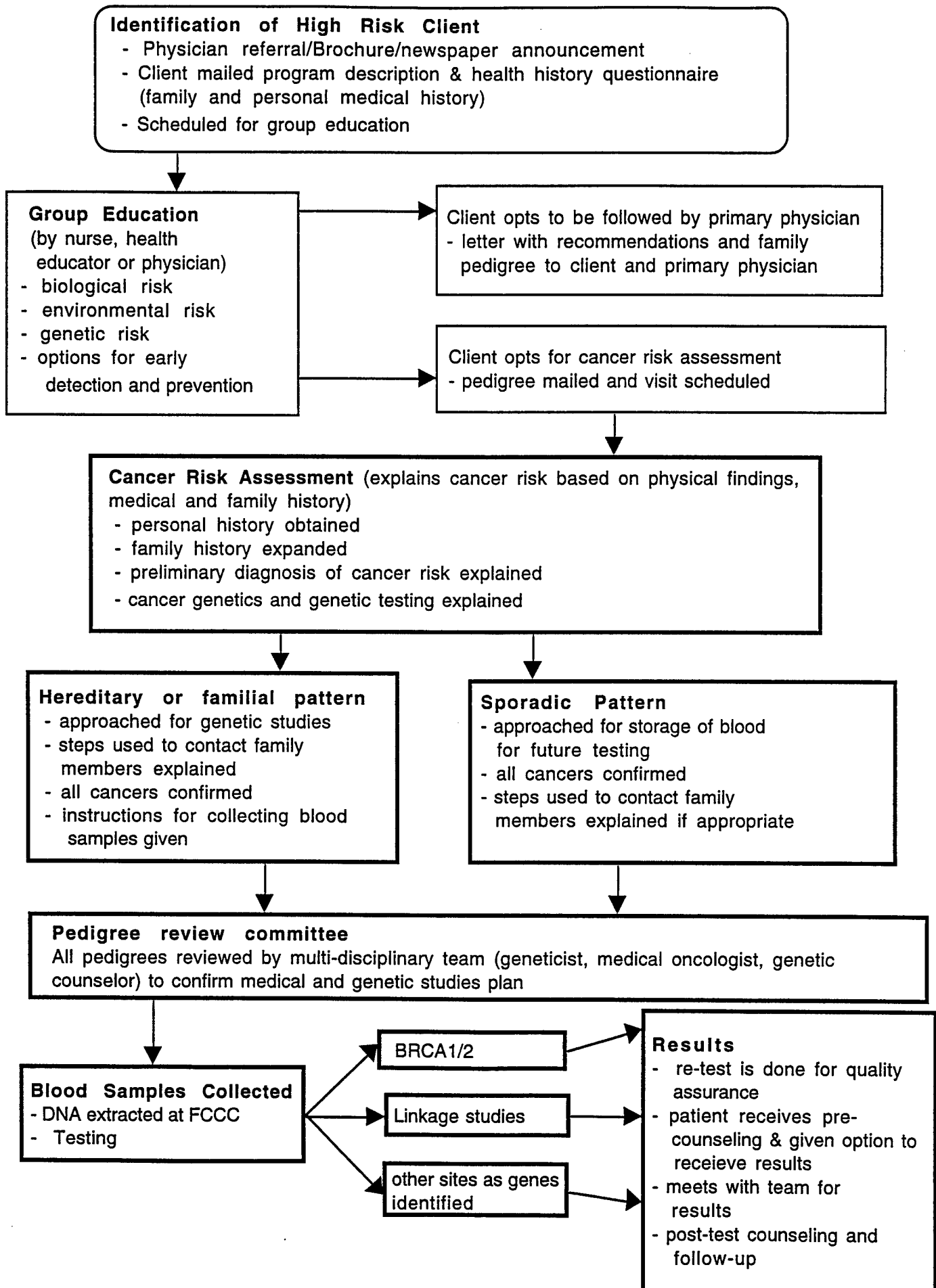
### **Section 4 - Procedures**

Pedigree Review  
Pedigree Review Recommendation Sample Form  
Pedigree Expansion/Individual Risk Assessment  
Familial Cancer Risk Counseling - Nursing Checklist  
Contacting Family Members for Blood and Tumor Samples for High Risk Registry  
Relative Identification Form for High Risk Registry  
Relative Contact Letter  
High Risk Registry Script  
Contacting Relatives for Medical Records or Tumor Samples  
Request for Authorization to Obtain Medical Records  
Instructions for Filling out Medical Records and Tissue Sample Form  
Authorization for Release of Medical Records and Tissue Material  
Letter to Medical Records Department  
Letter to Pathology Department  
Contacting Relatives for Blood Studies  
Blood Collection  
Blood Collection from a Relative Outside Network Hospital  
Lab Information Form  
Sample Pedigree  
Sample Federal Express Form  
Instructions for Packaging and Mailing Blood Samples  
Blood Donation Letter  
Sample Confidential Fax Cover Sheet  
Letter to Doctor to Obtain Blood Sample

## ADMINISTRATIVE

# Fox Chase Cancer Center

## Assessing Cancer Genetic Risk



**High Risk Registry**  
**Major Components of the Family Risk Assessment Process**

1. Identify individuals with a family history of cancer
  - Media
  - Physician Referral
2. Initial Phone Contact
  - complete baseline survey form
  - this documents call and appt date
3. Mail confirmation letter with Health History Questionnaire
4. Conduct group education
  - before session go over HHQ
  - at end of session complete form for physician name or interest in risk assessment
5. Send HHQ to FCCC
  - HHQ sent to Fox Chase where data is entered and pedigree generated
  - FCCC reviews before pedigrees returned and gives preliminary genetic diagnosis
  - Pedigrees mailed back to <Network Hospital>
6. Set up an individual session to work up pedigree
  - Individual or family meet with <staff> for Pedigree expansion and feedback
  - preliminary information on type of family cancer pattern provided
  - expanded pedigree sent to Fox Chase for Pedigree Review
7. Expanded pedigree is reviewed by multi-disciplinary team at Fox Chase:
  - a. confirms family cancer pattern
  - b. identifies further information to determine family cancer pattern
  - c. recommends medical or genetic studies plan
8. Feedback to family regarding medical follow-up or genetic studies
9. Families having genetic studies - bloods collected and sent to Fox Chase
10. Family given the option to receive results
11. Results given and follow-up provided

## **Genetic Cancer Risk Counseling Protocol (FCCC) for Hereditary Breast and Ovarian Cancer**

### **A. Entry into Program**

Entry into the Family Risk Assessment Program (FRAP) includes collecting sociodemographic, risk perception, and risk comprehension data, a personal medical history and a family history of cancer. Existing cancer screening practices are determined, and the consultand's general psychological adjustments, risk-specific psychological distress patterns, and existing coping styles are measured through a set of questionnaires.

It is at this point that a FRAP chart for the consultand is established

**Purpose:** As a first step for cancer risk assessment, sociodemographic, risk perception, and risk comprehension data, personal medical history and family history of cancer are collected. Existing cancer screening practices are determined, and consultand's general psychological adjustment, risk-specific psychological distress patterns, and existing coping styles are measured through a set of questionnaires.

1. Initial Contact (1 hour; via telephone)
  - a. FRAP Participant Contact Log
2. Baseline Assessment
  - a. Health History Questionnaire (HHQ)
  - b. Psychology surveys
  - c. Diet survey
  - d. FRAP chart for consultand established

## **B. Education Session (approximately 2 hours)**

At the initial educational session, basic information about the Family Risk Assessment Program is given. The education session provides information on the biological and environmental risk factors associated with breast and/or ovarian cancer. As well, the genetic factors associated with carcinogenesis, the influence of family history on one's risk for cancer, and the options available for prevention and early detection, are explained. An individualized carefully computed estimate of personal risk for breast cancer (the "Gail Model" score) is presented to the consultand attending the group education session for breast cancer. Each participant is invited to pursue further individualized assessment and counseling through the Family Risk Assessment clinic.

**Purpose:** Basic information about the Family Risk Assessment Program are given. The education session includes information on the biological and environmental risk factors associated with breast and/or ovarian cancer are provided in this session. As well, the genetic factors associated with carcinogenesis, the influence of family history on one's risk for cancer, and the options available for prevention and early detection, are explained. An individualized carefully computed estimate of personal risk for breast cancer (the "Gail Model" score) is presented to the consultand attending the group education session for breast cancer.

1. Education Session
  - a. Biological
  - b. Environmental
  - c. Genetic
  - d. Gail model score (presented during education session for breast cancer)
  - e. Descriptions of options recommended for early detection and prevention

**C. Triage: Preliminary Clinical Risk Diagnosis (performed 1 day prior to Individual Counseling Session)**

**Purpose:** Prior to the consultand's individual counseling session, the team members of FRAP formulate a preliminary clinical risk diagnosis based on an initial viewing of the family history. A cancer genetic family pattern/category of sporadic, familial, or hereditary is determined so that a plan for the appropriate type of cancer risk counseling strategy and testing research, best suited for the consultand, can be planned.

1. Triaging families

#### **D. Individual Counseling Session (approximately 1 hour)**

**Purpose:** During this session, detailed medical and family histories are obtained. Counseling is provided to explain risk for cancer based on findings from the medical and family histories. The current research to identify genes for breast and ovarian cancer, and how eligible individuals and their families can participate, are explained. Collection of blood and/or tumor samples from the consultand and from eligible family members is undertaken.

During the consultand's individual counseling session, the counselor obtains detailed medical and family histories. Using a computer generated pedigree as a working template, the family history is expanded. Confirmation of names, degree of relationship, and ages of relatives, and obtaining information on their medical, reproductive, and surgical histories are obtained. The consultand's personal medical history, including her reproductive history, medication and hormone usage, present occupation, lifestyle habits (smoking, alcohol, and drug usage) and about her general health, is documented.

Counseling is provided to explain risk for cancer based on findings from the medical and family histories. The genetics counselor explains the possible pattern or patterns of inheritance of cancers pertaining to the consultand's family history. Autosomal dominant inheritance, chromosomes, genes, and the concept of multifactorial reason for familial cancers (ie., multiple cancer susceptibility genes influenced by environmental agents) are described. The risks, benefits, limitations, and present status of genetic testing for cancer predisposition are explained. Issues of insurability and employability, cost of the test, and anticipated concerns within family members are explored.

Linkage analysis research to identify genes for breast and ovarian cancer in families, and how eligible individuals and their families can participate, are explained. If such research is feasible for the family, steps used in the collection of blood and/or tumor samples from the consultand and from family members eligible for linkage analysis, is undertaken, including an explanation on how these samples will be obtained and describing the medical consent forms.

It is at this point that a FRAP genetics chart for the consultand is established

1. Introduction - purpose of individual counseling session is explained
2. Personal medical history is obtained
  - a. general health (birth defects, heart, thyroid, history of surgeries, biopsies)
  - b. reproductive history
  - c. medication, hormone usage
  - d. smoking, alcohol, drug usage
3. Family history is obtained
  - a. a computer generated pedigree is used as working template
  - b. confirmation of names and ages of relatives
  - c. ethnicity and/or ancestral origins
  - d. consanguinity
  - e. confirmation of full sibship, relations
  - f. medical, reproductive, and surgical histories of family members
  - g. document environmental exposures (smoking, alcohol, work, war, etc.)
  - h. form(s) are signed to obtain medical records, when indicated
  - i. form(s) are signed to obtain tumor or biopsy tissue, when indicated
  - j. include recent changes to original HHQ and FRAP database



4. Cancer Genetics Counseling

- a. explain pattern of inheritance of cancers in consultand's family history
- b. autosomal dominant inheritance (how it pertains to family history)
- c. explain chromosomes, genetics, linkage analysis
- d. explain steps in linkage analysis process/protocol (letter announcing availability of results, pre-disclosure and disclosure sessions, follow-up)
- e. inform of risks, benefits, and limitations of results from genetic testing
- f. discuss concerns (confidentiality, insurance, psychosocial, impact of results)
- g. answer questions, discuss issues raised (feasibility, family dynamics, etc.)
- h. obtain informed consent and first blood sample from consultand

5. Contact family members for blood and/or tumor samples

- a. Relative Identification Form (RIF)
- b. Steps used to contact family member are explained:
  - i. letter accompanying blood collection kit and instructions
  - ii. instructions for collecting and mailing blood samples
  - iii. lab request for blood samples
  - iv. medical consent form
  - v. form to sign for release of medical records (if affected)
  - vi. form to sign for release of tumor sample (if affected)

## **E. Pedigree Review Committee Meeting**

A summary of the consultand's individual counseling session and information from her medical and family histories is presented. A clinical risk diagnosis based on this information is reviewed, evaluated, and finalized with this committee, which consists of a multi-disciplinary team of medical oncologists, oncology nurses, health educators, cancer genetics counselor and molecular geneticists. This team also helps to formulate follow-up recommendations for genetic investigation and counseling of all families seen by cancer genetics counselor.

Cases are reviewed periodically as new information is added to the data base.

**Purpose:** The consultand's medical and family histories and clinical risk diagnosis are reviewed, evaluated, and finalized with this committee, which consists of a multi-disciplinary team of medical oncologists, oncology nurses, health educators, cancer genetics counselor and molecular geneticists. This team also helps to formulate follow-up recommendations for genetic investigation and counseling of all families seen by cancer genetics counselor.

1. Pedigree Review Committee meeting.
  - a. information obtained from Individual Counseling Session is presented
  - b. confirming clinical risk diagnosis with Pedigree Review Committee
  - c. completing genetics consultation report
  - d. re-convene with Pedigree Review Committee as new information on consultand's medical and family histories are obtained

## F. DNA Analysis and Disclosure of Test Results (6 to 12 months)

A letter is sent out to the consultand announcing the availability of results from the genetic testing and is advised to call the genetics counselor up to schedule an appointment for a pre-disclosure counseling session. During this session, issues previously discussed in the individual counseling session are summarized. During this session, the counseling team helps the consultand(s) to examine anticipated psychosocial and emotional concerns and impact from positive or negative test results for her and her family. If test results are still wanted, the counselor determines the type of disclosure preferred by the consultand (phone, letter, physician, etc.) and a date for the disclosure of test results is arranged. Support systems available to the consultand are identified during this session.

Before the results are disclosed in the disclosure counseling session, the consultand is asked if the results are still wanted. The test results are communicated in an appropriate manner with adequate time for answering questions and concerns. Options for medical and psychological follow-up are re-evaluated. The consultand(s) is/are reminded of availability of support and information resources and of the possibility that genetics counselor will recontact and address future genetic risks as they become known.

**Purpose:** The pre-disclosure session serves to help the consultand examine anticipated psychosocial and emotional concerns and impact from positive or negative test results for her and her family. Role play is included as a form of cognitive-affective processing to help the consultand get in touch with the reality of the impact of these results to her family and to other family members.

1. Announcement of availability of test results
  - a. letter or phone call announcing test results available to be disclosed
  - b. appointment date for the pre-disclosure counseling session is arranged
2. Pre-disclosure counseling session (approximately 1 to 1 1/2 hours)
  - a Summary of BRCA1 genetic test (what is a gene, gene alteration, etc.);
  - b the risks and benefits of receiving an increased risk or a decreased risk for inheriting or carrying a cancer susceptibility gene;
  - c the risks and benefits of not receiving any results from this study;
  - d limitations of test results, possibility of error;
  - e early detection options;
  - f life and health insurance coverage;
  - g the issues of confidentiality among family members, friends, employers;
  - h relaying information to primary physician
  - i examine existing support systems, psychology referrals presently available (make appropriate referrals when indicated)
  - j Role play examining:
    - i the psychological impact of carrier status information
    - ii the psychological impact of non-carrier status information
    - iii the psychological impact for reasons to not know the results;
    - iv possible impact on family dynamics;
  - k ask if test results are still wanted
  - l determine type of notification of result for proband
  - m disclosure date of test results to proband is set-up

3. Disclosure of test results counseling session (approximately 1 to 1½ hours)

- a introduction
- b determine if results are still wanted
- c the result is communicated in the presence of oncologist, counselors
- d re-summarize implication of results
- e re-summarize preventative and early detection options
- f answer questions, concerns
- g inform of availability of genetics counselor and their support resources (referrals) to address issues and concerns as they arise
- h. inform possibility that genetics counselor will recontact and address future genetic risks as they become known
- i inform consultand of upcoming follow-up questionnaires

## G. Follow-up

Long-term follow-up is considered crucial for the medical and psychological well-being of individuals undergoing genetic testing. The purpose of the follow-up is to evaluate and report any changes in the consultand's previously measured general psychological adjustment, risk-specific psychological distress, and coping style. Up-to-date information/records on changes in medical and family histories since the disclosure of the test results are also obtained. Further information on adherence to recommended screening and preventive regimens, experiences with regard to issues of insurability, employability, and other potential forms of discrimination since the disclosure of genetic test results, is collected.

Contact is made by phone 1 week after disclosure of test results to clarify issues and identify acute problems and intervene when appropriate. Follow-up visits at 6 and 12 months are held to further assess medical, educational, and psychological needs. In addition, counseling support is made available on an ad hoc basis to address concerns as they arise. Access to physicians, a social worker, and psychologist, in addition to the genetics counselor, is available.

**Purpose:** To evaluate and report any changes in consultand's previously measured general psychological adjustment, risk-specific psychological distress, and coping style. Up-to-date information/records on changes in medical and family histories since disclosure of test results are obtained. Further information on adherence to recommended screening and preventative regimens, experiences with regard to issues of insurability, employability, and other potential forms of discrimination since disclosure of genetic test results, are obtained.

### 1. Short-Term Follow-up (1 to 2 weeks post-disclosure)

- a. Phone call or visit with cancer genetics counselor to discuss short term impact(s) of test results, change(s) in screening practices, follow-up with options, effectiveness and usage of psychological follow-up, etc.
- b. Questionnaire filled out when applicable.
- c. inform of availability of genetics counselor, medical, psychological, and support resources to address issues and concerns as they arise (referral for psychological assessment made here, when indicated)

### 2. Long-Term Follow-up (20 to 24 weeks post-disclosure)

- a. Phone call or visit with cancer genetics counselor to discuss long term impact(s) of test results, change(s) in screening practices, follow-up with options, effectiveness and usage of psychological follow-up, etc.
- b. Questionnaire filled out when applicable.
- c. re-inform of availability of genetics counselor, medical, psychological, and support resources (referrals) to address issues and concerns as they arise.

### 3. One Year Follow-up (50 to 54 weeks post-disclosure)

- a. Phone call or visit with cancer genetics counselor to discuss long term impact(s) of test results, change(s) in screening practices, follow-up with options, effectiveness and usage of psychological follow-up, etc.
- b. Questionnaire filled out when applicable.

### 4. Support sources (social worker, genetics counselor) available to individual as needed

## **IRB Approval for High Risk Registry Project**

### **1. Forms you will receive from Fox Chase**

a. FRAP Genetics Counseling Protocol with IRB approval

b. Consent forms

(1) ***Fox Chase Cancer Network Breast Cancer Risk Registry*** - this is sample form designed for those institutions that need a separate consent for collecting family and personal information that will become part of the risk registry

(2) ***Informed Consent to Participate in Research Studies #2*** - this is the first form given to those explaining the genetic testing research

(3) ***Informed Consent to Participate in Research Studies #3*** - this form is given to those who will be given the option to receive genetic testing results.

c. Disc with letters that are sent to participants regarding appointments, blood kits, requests for medical information.

2. You will need to adapt the informed consents and letters to meet the need of your institution and submit for review to your IRB.

### **3. Requirements for IRB**

a. Protection of Human Subjects form #310 or #9999.

b. Protocol

c. Informed Consents

d. Letters that will be explaining participation in the various aspects of the Registry (these letters may not need the IRB stamp, but it is helpful for the IRB to see all materials that participants will be receiving)

### **4. Requirements for Fox Chase**

a. keep your own file of all your IRB correspondence and approvals

b. send to FCCC

(1) copy of 310 form

(2) IRB minutes

(3) IRB approved consent forms

(4) copy of any approved revisions

## **DISCLAIMER NOTICE**

The FRAP forms enclosed in this disc have been developed and approved for the Fox Chase Cancer Center, Margaret Dyson Family Risk Assessment Program. The IRB approval for the consent forms and letters cover the Fox Chase Cancer Center program only. Therefore, these documents are to serve as samples for you. They will need adaptation for your program and the IRB approval of your institution.

## **Informed Consent Samples for High Risk Registry Program**

There are **3** samples of informed consents for your use, depending on the requests of your respective IRB:

- One for the Registry itself - this can be used if your IRB needs a more formal consent to collect data than what is on the Health History Questionnaire.
- ELSI consent #2 - this is for those donating blood for the genetic research study.
- ELSI consent #3 - this is for those who will be receiving results. This form is completed during a pre-disclosure counseling session



## **Fox Chase Network Breast Cancer Risk Registry**

### **Introduction**

You have been asked to participate in a Registry of women who are relatives of women with breast cancer. This study will help researchers learn more about the causes of breast cancer and how it concentrates in some families. It will help us to determine who is at a higher risk for breast cancer, and will allow us to give more personalized recommendations to women about their risk and what kinds of prevention programs might work best for them.

### **Purpose**

The purpose of this study is to collect, in a computerized registry, information about family history, medical, and risk factors from women with one or more relatives with breast cancer to learn better ways to predict future risk and to understand the causes of breast cancer. Information is also collected regarding feelings about cancer to help us learn more about the impact of risk for cancer.

### **Procedures**

If you agree to be in this program, you will be asked to fill out a series of questionnaires about your own family history, medical history, lifestyle and other factors that may pertain to risk for breast cancer. You will receive a copy of your family tree, called a pedigree, and feedback concerning your risk for breast cancer, and preventive recommendations you might take, such as mammography screening. You will be asked to update the information on a yearly basis, so that over time, we can learn more about the causes of breast cancer. Also it provides an opportunity to inform you if there is any change in your risk status.

### **Risk**

The only possible risk is increased anxiety related to cancer risk.

### **Alternatives**

The alternative would be to not participate in the study.

### **Potential Benefits**

It is unknown if you will derive any personal benefit from the study. However, information gained from the study may benefit other members of your family and other women in the future.

### **Confidentiality**

All the information that you provide will be kept confidential. A code number will be used to enter and track any information about you and your family and your name will not be used.

### **Research Rights**

If you have any questions regarding this study or your rights, you can contact Mary Daly, MD, PhD., Principal Investigator at (215) 728-2891 or Institutional Review Board of <Network Institution> at <phone>.

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Signature

---

Witness

---

Date

## Informed Consent to Participate in Research Studies

- 1 **Title of Study:** Genetic Testing Research Study for Predisposition to Hereditary Forms of Cancer.
- 2 **Principal Investigators:** Mary B. Daly, MD, PhD  
Andy Godwin, PhD  
Josephine Costalas, MS  
Family Risk Assessment Program  
Fox Chase Cancer Center  
510 Township Line Road  
Cheltenham PA 19012  
tel: (215) 728-2704 or (800) 325-4145
- 3 **Purpose:** The purpose of this genetic testing research study is to look for alterations in genes that may be related to a higher risk (predisposition) of cancer. Having a family history of breast, ovarian, colon, or other types of cancer, can increase a person's risk for developing these types of cancer. Research has shown that 5 to 10% of cancers are hereditary. This means an alteration in a cancer predisposition gene (that is, this gene has a mistake) is passed on from parent to child. Scientists have begun to find that alterations in these cancer predisposition genes can increase an individual's chances of developing breast, ovarian, colon and/or other types of cancer. More research will help us to learn about other alterations in genes that can lead to cancer, and how often these alterations happen.
- 4 **Procedures:** The individual providing the genetics information in this genetic testing research study is a health professional trained in cancer risk counseling. This person is trained in the genetic assessment and counseling of individuals at genetic risk for cancer and are participating in genetic testing research studies. If I agree to participate in the first phase of this genetic testing research study, I will give my medical history and my family's history of cancer to the health professional trained in cancer risk counseling. I will have about 15 to 30mls of my blood (about 2 to 4 tablespoons) taken from a vein in my arm . I may feel some discomfort when the technician takes my blood sample. The only possible risks are a bruise at the needle site and, rarely, a feeling of faintness. This needle site usually heals within two days.

**4 Procedures (continued)** The staff at Fox Chase Cancer Center (FCCC) handling my sample of blood for this genetic testing research study will keep these samples and the results from this genetic testing research study in a carefully supervised laboratory. When this genetic testing research study is completed and informative, I will be notified to participate in the second phase of this study and be given the opportunity to receive the results with genetic counseling. I can choose whether or not I want to receive my results. The health professional trained in cancer risk counseling will give me important information to help me to decide if I would like to receive these results or not. As explained to me by the health professional trained in cancer risk counseling, if I choose not to receive my test results, I will not receive information about these results. If I choose to receive my test results, a second sample of my blood will be considered for the second phase of this genetic testing research study (preparation to receive the results) based on the careful evaluation of the pattern of cancers in my family history and on the availability of a sample (blood or tissue) from myself (if I have a personal diagnosis of cancer) or from one of my close relatives diagnosed with cancer. I understand that there is no guarantee that this study will be completed or informative and that results from this study will take a very long time to

**5 Benefits:** There are no direct benefits to myself or my family members at this time for participating in this genetic testing research study. I may, however, take pride in the fact that my contribution may help to better understand the science related to cancer. I understand that this is not a diagnostic test; all blood samples will be used for the purpose of this genetic testing research study only. As explained to me by the health professional trained in cancer risk counseling in the procedures section of this consent form, when this genetic testing research study is completed and informative, I will be notified to participate in the second phase of this study and be given the opportunity to receive the results with genetic counseling.

**6 Alternatives:** The alternative to participating in this genetic testing research study is to not participate.

**7 Confidentiality:** The staff handling my sample of blood for this genetic testing research study will keep the results in strict confidence. The staff will use a code number instead of my name when researching my blood sample. This code number will also be used for research and/or education purposes in all scientific publications and/or presentations so only the principal investigators of this study will be able to identify me or my family. Any results from this study will not be included in my medical record, and will not be available to any other parties, for example, to insurance companies or to employment agencies.

**8 Limits on Confidentiality:** I understand that the staff handling my sample of blood for this genetic testing research study will try its best to protect my confidentiality. However, if there was a litigation (a lawsuit) involving my illness, or my employer, or any issue related to why I developed a certain illness, or wanted surgery for preventive reasons, the results from this genetic testing research study could be considered relevant information in the suit. A judge, in a court of law, related to this lawsuit, could issue an order to disclose the results from my participation in this genetic testing research study and any medical and non-medical information considered relevant to the lawsuit.

**9 Costs:** The billing process for my participation in this genetic testing research study has been explained to me in the educational session. Since the purpose of this study is still in the research stage, I will not be charged for the cost of my participation in this study. The counseling sessions with the health professional trained in cancer risk counseling are free of charge, for as long as needed. Any clinic visits, treatments, physical exams, and/or diagnostic tests I have done at Fox Chase Cancer Center will be billed to my insurance company. I will be responsible for covering the costs associated with any referrals made to me or my family member(s) for medical, psychological, and/or support care.

**10 Compensation:** There is no cost nor payment to me for my participation in this genetic testing research study. Participation in this study does not include payment for any medical and psychological care, treatments, and/or diagnostics tests generated outside of this study. I fully understand that if I suffer personal injury as a result of my participation in this study, no payment is or will be available for payment of my lost wages or other losses, including employment and insurance coverage losses.

**11 Withdrawal and Termination:** Participation in this genetic testing research study is voluntary. I am free to withdraw my consent and discontinue participation in this study at any time without prejudice or effect to me or my family's present or subsequent medical care and access to genetic counseling. No genetic test results will be given to me without my permission. All information will remain and be kept in strict confidence.

**12 Voluntary Consent:** If I am not satisfied with the manner in which this genetic testing research study is being conducted, I may report (without giving my name if I so choose) any complaints to the Institutional Review Board by calling (215) 728-2931, 9:00 a.m. to 5:00 p.m., Monday to Friday, or by addressing a letter to the Institutional Review Board, Fox Chase Cancer Center, 7701 Burholme Avenue, Philadelphia, PA 19111. For other questions concerning this study, I may contact the principal investigator listed above. By signing below, I agree that I have read this form, received acceptable answers to my questions, and have agreed to participate in this genetic testing research study, as described above. I will receive and keep a copy of this form.

**13** \_\_\_\_\_  
Name of Participant

**14** \_\_\_\_\_  
Signature of Participant Date

**15** I have explained the terms and conditions of the consent form of this genetic testing research study to the above participant and based on this conversation, I believe he/she has understood what was discussed.

**16** \_\_\_\_\_  
Signature and title of counselor Date

## Informed Consent to Participate in Research Studies

- 1 **Title of Study:** Genetic Testing Research Study for Predisposition to Hereditary Forms of Cancer.
- 2 **Principal Investigators:** Mary B. Daly, MD, PhD  
Andy Godwin, PhD  
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- 3 **Purpose:** The purpose of this genetic testing research study is to look for alterations in genes that may be related to a higher risk (predisposition) of cancer. Having a family history of breast, ovarian, colon, or other types of cancer, can increase a person's risk for developing these types of cancer. Research has shown that 5 to 10% of cancers are hereditary. This means an alteration in a cancer predisposition gene (that is, this gene has a mistake) is passed on from parent to child. Scientists have begun to find that alterations in these cancer predisposition genes can increase an individual's chances of developing breast, ovarian, colon and/or other types of cancer. More research will help us to learn about other alterations in genes that can lead to cancer, and how often these alterations happen. Individuals who have cancer in their family can participate in a genetic testing research study to see if they have inherited an alteration on certain cancer predisposition genes. Knowing if an individual carries an alteration in a cancer predisposition gene can help to determine what cancer screening tests for the doctor to recommend, and when to have these tests.
- 4 **Procedures:** The individual providing the cancer genetics information in this genetic testing research study is a health professional trained in cancer risk counseling. This person is trained in the genetic assessment and counseling of individuals at genetic risk for cancer and are participating in genetic testing research studies. If I agree to participate in the second phase of this genetic testing research study, I will have about 15 to 30mls of my blood (about 2 to 4 tablespoons) taken from a vein in my arm. I may feel some discomfort when the technician takes my blood sample. The only possible risks are a bruise at the needle site and, rarely, a feeling of faintness. This needle site usually heals within two days. The staff at Fox Chase Cancer Center (FCCC) handling my sample of blood for this genetic testing research study will keep these samples and the results from this genetic testing research study in a carefully supervised laboratory.

**4 Procedures (continued)** The health professional trained in cancer risk counseling will give me important information to help me to decide if I would like to continue to receive these results or not. When the genetic testing research study on my second sample of blood is completed and informative, I will be notified and be given the opportunity to receive the results with genetic counseling. I can choose whether or not I want to receive my results. As explained to me by the health professional trained in cancer risk counseling, if I choose not to receive my test results, I will not receive information about these results at this time. If I choose to receive my test results, an appointment will be set up. The physician, the health professional trained in cancer risk counseling, and a social worker will be present when the results from this genetic testing research study are given to me and an additional consent form will be signed to acknowledge that I have received the results. I have the option of choosing someone (spouse, close friend, close relative) to be with me at the time of this appointment. I understand that there is the possibility that the cancer health professional trained in cancer risk counseling will recontact me and go over future genetic risks as they become known.

**5 Potential Limitations:** I understand that the results from this genetic testing research study are not 100% accurate. A negative study result (meaning, no alteration in a cancer predisposition gene is found) does not eliminate the chance that I might have an alteration in another cancer predisposition gene which has not yet been discovered and I am still at some risk of developing cancer. Likewise, a positive test result (meaning, an alteration in a cancer predisposition gene is found) does not mean that there is a guarantee that I will develop cancer. Although I will be given recommendations about early detection methods based on my test results, I realize that they are still preliminary, and may change as time goes on.

**6 Potential Benefits:** By examining a sample of my blood in this genetic testing research study, it may be possible to determine if I have inherited an alteration in a cancer predisposition gene. As explained to me by the health professional trained in cancer risk counseling in the procedures section of this consent form, I will have the option to receive the results with genetic counseling when this study is complete and informative. The benefits of knowing my results may increase my awareness and/or decrease my anxiety about my risk for developing cancer by giving me a more reliable estimate of my risk. I will be counseled on what cancers I would be at risk for, and about the options available to me for screening, and early detection of these cancers, and for prophylactic surgery. I will also have a more reliable estimate risk for passing an alteration in a cancer predisposition gene to my children or sharing it with one of my family members. The results from this study could help encourage other members of my family to participate in a study such as this one and seek genetic counseling about their risk for cancer.

**7 Potential Risks:** I understand that at present, not much is known about how knowing the results from this genetic testing research study for cancer predisposition could affect one's employment and insurance (life, health, and/or disability insurance). There is a possibility of discrimination if I test positive (that is, I carry an alteration in a cancer predisposition gene). The discrimination may include, but not be limited to: an increase in rates of current insurance policies, cancellation of existing policies, or difficulty in obtaining new life, health, or disability insurance policies when changing jobs. Insurance companies and/or employers may in the future decide to ask me if I have ever received results related to my risk for cancer when I apply for a new policy or a new job. As well, learning about the results from this study may create tension and confusion between members of my family. There is also the risk that I may become more anxious and fearful about my risk and my family members' risk for developing cancer based on the results from this study.

**8 Confidentiality:** The staff at Fox Chase Cancer Center handling my sample of blood for this genetic testing research study will keep the results in strict confidence. The staff will use a code number instead of my name when researching my blood sample. This code number will also be used for research and/or education purposes in all scientific publications and/or presentations so only the principal investigators of this study will be able to identify me or my family. Any results from this study will not be included in my medical record, and will not be available to any other parties, for example, to insurance companies or to employment agencies. As explained to me earlier, I can choose whether or not I want to receive results from this study.

**9 Limits on Confidentiality:** I understand that the staff handling my sample of blood for this genetic testing research study will try its best to protect my confidentiality. However, if there was a litigation (a lawsuit) involving my illness, or my employer, or any issue related to why I developed a certain illness, or wanted surgery for preventive reasons, the results from this genetic testing research study could be considered relevant information in the suit. A judge, in a court of law, related to this lawsuit, could issue an order to disclose the results from my participation in this genetic testing research study and any medical and non-medical information considered relevant to the lawsuit.

**10 Alternatives:** The alternative to participating in this genetic testing research study for predisposition to cancer is to estimate my risk for cancer based on other known contributing causes, such as my age, family history of cancer, pregnancy history, and other factors. I will receive recommendations for screening tests for certain kinds of cancer. I will have time to ask questions related to the benefits, risks, and limitations of these choices.

**11 Access to Support Resources:** The individual providing the cancer genetics information in this genetic testing research study is a health professional trained in cancer risk counseling. This person is trained in the genetic assessment and counseling of individuals at genetic risk for cancer and are participating in genetic testing research studies. This counselor will be able to make referrals to medical, psychological, and support resources to address issues and concerns as they arise before and after I receive results from this study. My family and I will have access to these support services both immediately after I learn the results from this study and in the months following, as needed.

**12 Costs:** The billing process for my participation in this genetic testing research study has been explained to me in the educational session. Since the identification of alterations in genes related to cancer predisposition is still in the research stage, I will not be charged for the cost of my participation in this study. The counseling sessions with the health professional trained in cancer risk counseling are free of charge, for as long as needed. Any clinic visits, treatments, physical exams, and/or diagnostic tests I have done at Fox Chase Cancer Center will be billed to my insurance company. I will be responsible for covering the costs associated with any referrals made to me or my family member(s) for medical, psychological, and/or support care.

**13 Compensation:** There is no cost nor payment to me for my participation in this genetic testing research study. Participation in this study does not include payment for any medical and psychological care, treatments, and/or diagnostics tests generated outside of this study. I fully understand that if I suffer personal injury as a result of my participation in this study, no payment is or will be available for payment of my lost wages or other losses, including employment and insurance coverage losses.

**14 Withdrawal and Termination:** Participation in this genetic testing research study is voluntary. I am free to withdraw my consent and discontinue participation in this study at any time without prejudice or effect to me or my family's present or subsequent medical care and access to genetic counseling. No genetic test results will be given to me without my permission. All information will remain and be kept in strict confidence.

**15 Voluntary Consent:** If I am not satisfied with the manner in which this genetic testing research study is being conducted, I may report (without giving my name if I so choose) any complaints to the Institutional Review Board by calling (215) 728-2931, 9:00 a.m. to 5:00 p.m., Monday to Friday, or by addressing a letter to the Institutional Review Board, Fox Chase Cancer Center, 7701 Burholme Avenue, Philadelphia, PA 19111. For other questions concerning this study, I may contact the principal investigator listed above. By signing below, I agree that I have read this form, received acceptable answers to my questions, and have agreed to participate in this genetic testing research study, as described above, to have my risk for carrying an alteration in a cancer predisposition gene assessed. I will receive and keep a copy of this form.

**16** \_\_\_\_\_  
Name of Participant

**17** \_\_\_\_\_  
Signature of Participant

\_\_\_\_\_ Date

**18** I have explained the terms and conditions of the consent form of this genetic testing research study to the above participant and based on this conversation, I believe he/she has understood what was discussed.

**19** \_\_\_\_\_  
Signature and title of counselor

\_\_\_\_\_ Date



## MARKETING

# Protocol Alert

FOX CHASE  
CANCER CENTER

NEW ONCOLOGY PROTOCOLS FOR CLINICAL STAFF



Genetic testing is a hot issue today. As discoveries of mutations in human genes advance the science of cancer care, health professionals find themselves contemplating many ethical issues.

Today, genetic testing for hereditary cancers is conducted only in asso-

ciation with research. The impact of genetic test results can be quite powerful and requires education and counseling to emphasize the "predisposition to cancer" rather than the "predictor of cancer" label.

The Margaret Dyson Family-Risk Assessment Program and the Breast-Cancer Risk Registry at Fox Chase Cancer Center provide information and counseling to women at increased risk of breast cancer.

Each woman's primary physician is informed about her risk so an appropriate plan of care can be determined.

For more information, call our Physicians Services Line, 1-800-322-2144.

Mary B. Daly,  
M.D., Ph.D.

Director,  
Margaret Dyson Family-  
Risk Assessment Program

## New Study for Pancoast Tumors of the Lung

Carcinoma of the lung continues to be among the most common and lethal tumors in the U.S. It is expected that 170,000 new cases will be diagnosed this year and 150,000 people will die of this disease. Lung cancer is now the leading cause of cancer morbidity in women, surpassing breast cancer.

Whenever possible, surgical resection is offered to patients with non-small-cell lung cancer. Often chemotherapy or radiation is employed when surgery is not feasible.

A rare presentation of non-small-cell lung cancer is a tumor in the superior sulcus of the lung. The tumor,

## Update: Breast Cancer Genes

A susceptibility gene for breast cancer was definitely identified last year by positional cloning methods on the long arm of chromosome 17. Known as BRCA1, it appears to be responsible for disease in 45% of families with multiple cases of breast cancer only and up to 90% of families with both breast and ovarian cancer. In these families, the cumulative risk of breast cancer in women with a mutant BRCA1 gene is estimated to be 73% by age 50 and 87% by age 70.

There is also preliminary evidence that carriers of the mutant

BRCA1 gene may be at risk for colon and prostate cancer. To date, a total of 80 mutations of BRCA1 have been identified in DNA samples from women with familial and sporadic breast and/or ovarian cancer. These mutations are likely to result in missing or non-functional proteins, supporting speculation that BRCA1 is a tumor-suppressor gene.

The frequency of mutations in BRCA1 is thought to be as high as 1 in 300 in the general population. New evidence suggests that specific BRCA1 mutations may occur in 1 of every

100 Ashkenazi Jews.

A second breast-cancer susceptibility gene, BRCA2, has been localized to the long arm of chromosome 13. This gene appears to confer a high risk of predominantly early-onset breast cancer and may account for some hereditary causes of male breast cancer.

Breast cancer is also a component of the rare Li-Fraumeni syndrome, in which a germ-line mutation of the p53 gene on chromosome 17q has been documented.

The identification and location of these breast-cancer genes permits further investigation of the precise role they play in cancer.

Fox Chase Network's Breast-Cancer Risk Registry is one research

initiative expanding our knowledge about the modifiable causes of breast cancer. The Risk Registry program will collect genetic and environmental risk information from patients with familial breast cancer and from women at increased risk due to family history.

The program will also help test the best ways to

provide information and counsel high-risk women and their primary-care providers. By participating in this research, each Network hospital can help bring advances in cancer genetics into community-based cancer control and prevention programs. See the reverse side for more information about the Risk Registry.

FOX CHASE  
CANCER CENTER

Physicians Services Line  
1-800-322-2144

# Breast-Cancer Risk Registry Starts Up

Fox Chase Network's Breast-Cancer Risk Registry completed its first year of work in September 1995, by laying the foundation for implementation and recruitment. Tasks accomplished included:

- A family-risk assessment tool to collect family, personal and medical risk data was developed.
- The genetic testing facility at Fox Chase Cancer Center is now ready to provide molecular and genetic tests to identify germ-line mutations in registry participants who have been identified at risk of familial breast or ovarian cancers.
- Breast-cancer risk education materials—either color slides or prints and a script—are now available on Macintosh disc. These educational tools will help to inform women about genetic risk of breast cancer and recruit high-risk individuals into the Risk Registry.
- Ten Network nurses from eight hospitals were trained in the Familial-Cancer Risk Counseling Course in May 1995. (Mark your calendars: Our next training is January 16-18, 1996.)
- Five Network hospitals helped develop procedures and recruitment strategies through meetings with their medical directors and staff.
- Delaware County Regional Cancer Center piloted the first education and recruitment session with 15 women from four families with a history of breast cancer.

With this groundwork completed, the Risk Registry program enters its second year ready to proceed with recruitment and evaluation of breast-cancer risk-assessment interventions at Network hospitals. For more information, call risk project manager Agnes Masny, R.N., M.P.H., (215) 728-2892.

## Tumors continued

traditionally termed a "Pancoast tumor," frequently presents with a classical syndrome of shoulder or arm pain, neurologic changes at C-8 and T-1, and Horner's syndrome.

In the past, these tumors were felt to be inoperable. Over the last 30 years, preoperative radiation therapy has been employed with five-year survival of 20% to 30%. New attempts at innovative therapy are needed if a more signifi-

cant impact on this tumor is to be made.

Due to the rarity of this tumor, accounting for only 3% of lung tumors, a national study needs to be done to assess adequately the benefit of a new treatment. Fox Chase Network will participate with other national cooperative groups in a new Phase II study for Pancoast tumors.

This trial, E-S9416, will initially treat patients with two cycles

of chemotherapy (cisplatin and VP-16) given concurrently with radiation therapy. Patients with stable or improved disease will then undergo surgical resection. Following surgery, an additional two cycles of chemotherapy will be given.

We hope this combined modality approach will provide patients with good local control of their tumor as well as prevent distant metastatic disease.

## Chemotherapy for Small-Cell Lung Cancer

About 35,000 new cases of small-cell lung cancer will be diagnosed this year in the U.S. Although this tumor is highly sensitive to chemotherapy, often leading to dramatic and beneficial remissions, most patients will develop recurrent disease within a year and die of metastatic disease.

In particular, patients who present with extensive disease (disease outside of one hemithorax) will inevitably die of

recurrent disease no matter what response they have to chemotherapy. Many different approaches are being explored to improve the prognosis of these patients. Most include systemic chemotherapy.

One such approach now being evaluated and available to Fox Chase Network hospitals is an ECOG study, E-7593. In this study, patients with extensive small-cell carcinoma will initially receive cisplatin and VP-

16 for four cycles.

Patients who have stabilized or improved will randomly receive either no further therapy or topotecan every three weeks for four to six cycles. Topotecan has shown promise in this disease in previous studies, where approximately 34% of patients had a response to treatment. The treatment does not require hospitalization and should be generally well-tolerated.

## Fox Chase Cancer Center

FOX CHASE  
CANCER CENTER

Discovery & Hope  
1-800-322-2144

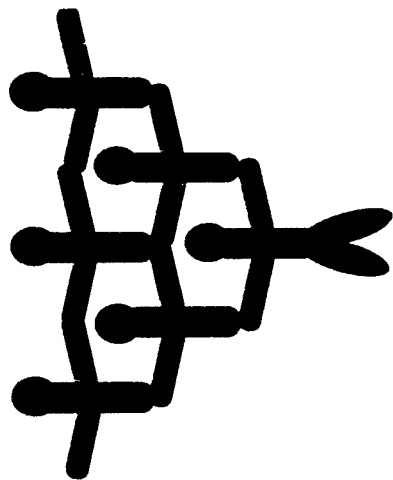
Robert F. Ozols, M.D., Ph.D.  
Senior Vice President  
Medical Science  
Fox Chase Cancer Center

Richard Scher, D.O.  
Associate Medical Director  
Fox Chase Network  
Editor, Protocol Alert

Contributors: Mary B. Daly, M.D., Ph.D.  
Agnes Masny, R.N., M.P.H.

For Cancer Information or to use PDQ  
(Physician Data Query), call 1-800-4-CANCER.

"DRAFT"



What your  
*family history*  
can tell you  
about cancer.

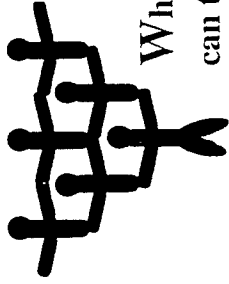
## Some cancers can run in families

Studies have shown that certain cancers may be hereditary (run in families). Breast and ovarian cancer, colon, uterine, skin and prostate cancers are some of the cancers that can run in families.

Doctors are trying to better understand the hereditary factors or genes that can influence the risk for cancer. By finding changes or alterations in genes that can be passed from one generation to the next, we are learning what can make a person more susceptible to getting a hereditary cancer.

## Knowing your family history can help

Having a family history of cancer (some one in your family with cancer) can increase the risk of getting a cancer. But most cancers are not hereditary. Often a common lifestyle, diet, or environment are reasons. Knowing your family's history of cancer can tell you how much of your cancer risk is due to hereditary factors and how much is due to environmental and lifestyle factors.



## What your family history can tell you about cancer...

Answer the questions below to find out if you need more information about your risk for hereditary cancer.

- ◆ Have you, or any of your immediate family (your parents, children, brothers or sisters) ever had cancer?  
☐ Yes ☐ No
- ◆ Was there ever a cancer in your close blood relatives: your grandparents, your mother's or father's brothers and sisters, or nieces, nephews, and cousins?  
☐ Yes ☐ No
- ◆ Did any of the cancers in your immediate family or your close blood relatives happen before the age of 50?  
☐ Yes ☐ No

*If you answered yes to one or more of these questions you may need more information about risk for hereditary cancers.*

**Learn more about hereditary cancer**  
To learn more about your family history and cancer, fill in the information below and give it to your doctor.

You will receive information about hereditary cancer and how to collect information about your family's cancer history.

***You will have the opportunity to have:***

- ◆ A detailed evaluation of your family history of cancer
- ◆ Education about risk for cancer and what you can do.
- ◆ The option for genetic testing will be discussed with eligible individuals.

-----  
Please print

Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Phone \_\_\_\_\_

Your doctor \_\_\_\_\_

# *Family Risk Assessment Program*

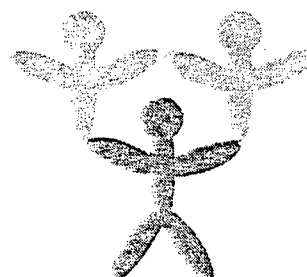
New Program to Identify Breast Cancer Risk

## **For More Information**

For more information about this program, call the Risk Assessment Counselor at Paoli Memorial Hospital, 610-648-1608.

**THE CANCER CENTER**  
OF PAOLI MEMORIAL HOSPITAL & FOX CHASE CANCER CENTER  
**PAOLI MEMORIAL HOSPITAL**

3/96



**THE MARGARET DYSON**  
**Family Risk Assessment Program™**

**THE CANCER CENTER**  
OF PAOLI MEMORIAL HOSPITAL & FOX CHASE CANCER CENTER  
**PAOLI MEMORIAL HOSPITAL**

**S**tudies show that certain cancers may be hereditary, or "run in families." Breast, ovarian, colon, uterine, skin and prostate cancers are some of the cancers that can be hereditary. Five to ten percent of breast cancers are due to presently known genetic factors that are passed on from one generation to the next.

## **Heredity and Research**

Scientists are trying to understand these hereditary factors, or genes, that can influence the risk for cancer. By finding changes or alterations in genes passed from one generation to the next, we learn what can make a person more susceptible to hereditary cancers.

## **Family Risk Assessment Program**

The program's goal is to help women learn more about risk factors associated with breast cancer. This free program provides participants with up-to-date information on the familial patterns of these cancers and information on how pregnancy history, hormone use and diet may be related to breast cancer. Participants learn about screening guidelines and prevention options.

## **Eligibility**

Women with a family history of breast cancer are eligible for the Family Risk Assessment Program. Participants should be at least 20 years old and have at least one first-degree relative—mother, sister or daughter—with breast cancer.

## **Program Features**

The program offers education and counseling tailored to the individual needs of each woman, based on her medical and family history. The program includes:

- a two-hour, group information session on breast cancer;
- an explanation of the known risk factors for breast cancer and how they work;
- a detailed evaluation of the family history;
- a description of recommended screening tests and personalized screening recommendations;
- instruction in breast self-examination techniques, if desired; and
- the option to participate in genetic research and testing through Fox Chase Cancer Center for eligible individuals.

The current research to identify genes for breast cancer will be explained to program participants. As genes are identified, eligible individuals and their families may have the option to have a blood test to determine if they have inherited a cancer gene. Options for early detection and prevention of cancer also are discussed.

## **The Cancer Center**

The Cancer Center at Paoli Memorial Hospital is affiliated with the Fox Chase Cancer Center through the Fox Chase Network. The Fox Chase Network is a select group of community hospitals that work cooperatively with Fox Chase Cancer Center to provide the latest in cancer prevention, diagnosis and treatment to people in their own communities.

## RECRUITMENT



FCCC  
Participant ID # \_\_\_\_\_

FRAP - \_\_\_\_\_, \_\_\_\_\_

## Participant Contact Log

### Baseline Survey

Name :

Address :

Telephone Number :

Best time to call:

Date of Birth :

Patient's Name :

Relationship to patient :

Date letter sent :

Date	Time of Attempt	Time of Completion	Disposition	Initials
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

### Comments

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# High Risk Registry Program

## Telephone Script

Hello. My name is \_\_\_\_\_ and I'm calling from the  
<Network Hospital> High Risk Registry Program for relatives of women with  
(breast/ovarian) cancer.

*Case 1: Because you have a family member with breast cancer, you have recently requested  
information about your risk of developing cancer...*

*Case 2: Your name has been given to us by \_\_\_\_\_. (He/She/They)  
thought you may be interested in our program because of your family history-of cancer.*

*Case 3: Your physician has recently recommended that we contact you because of your family  
history of breast cancer... (optional: because of your personal history of breast cancer).*

Do you have a few minutes to talk with me now about our program?

*If not convenient...*

*-- arrange to call back*

*-- if woman is definitely not interested in discussing the program, thank her for her time and  
terminate the call (probe for reasons, check below).*

*If no, thank woman for her time and terminate the call...(explore and check response)*

- \_\_\_\_\_ No Time
- \_\_\_\_\_ Lives too far away
- \_\_\_\_\_ Doesn't think it's important for her
- \_\_\_\_\_ Concerned about cost
- \_\_\_\_\_ Doesn't want to talk about cancer
- \_\_\_\_\_ Doesn't feel at increased risk
- \_\_\_\_\_ Can't come to FCCC
- \_\_\_\_\_ Is being screened regularly
- \_\_\_\_\_ Family wouldn't approve
- \_\_\_\_\_ Other \_\_\_\_\_

*If yes, continue...*

First of all, can you tell me a little bit about your family history of cancer, and then I'll explain our program to you and you can tell me whether or not it's something you would be interested in.

Family History: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

*1) (if woman has no family history of cancer, tell her the program is designed for women with a family history of cancer and would probably not be appropriate for her). Probe for concerns... Refer to appropriate source.*

*2) If woman has personal history of breast cancer, tell her the program is for her relatives who do not have cancer, but there would be important information for her as well.*

*3) If has appropriate family history, continue...*

Now I'll explain our program to you.

Our program is designed to help give women like yourself information about their risk for (breast/ovarian) cancer based on their family history in addition to information about any other cancers which might have a family association. The program consists of a one and a half to two hour group educational session with a health professional from the Fox Chase Network. The group educational session will go over breast cancer and what it means to you because of your family history, the risk factors associated with breast cancer, as well as important information on issues such as diet, birth control and hormone replacement therapy, smoking and alcohol. If you have concerns regarding preventive surgery, this can also be addressed. We'll also discuss what risk there may be in the future for other members of your family, such as your children.

We will provide the latest information regarding genetics and cancer. We will provide an overview of what we are looking for in families, the progress that is being made in this area and what this means to you and your family.

This session also involves an explanation of the various screening exams for breast cancer and other important cancers, and information on their accuracy. We will then recommend a series of screening exams that are the most appropriate for you based on your age and family history.

The educational session is <cost arrangement>. We just ask women to complete a questionnaire for research, and this questionnaire will help us to give you feedback about your risk for breast cancer. If you decide to come in, I will mail the questionnaire to you ahead of time and ask that you bring it in with you to your visit.

Following the educational session, there is the opportunity to:

- come into <Network hospital> and meet with one of our nurses trained in Familial Cancer Risk Assessment;

- receive your family pedigree, a family tree that looks at the cancer across several generations;

- get feedback about the family pattern of cancer and what it means for you.

This is not a requirement, however, and you can make this decision after you have attended the session.

Do you think you would be interested in participating in such a program?

(1) \_\_\_\_\_ Yes (continue on next page)

(2) \_\_\_\_\_ No (thank for time and close)

(3) \_\_\_\_\_ Not Sure \_\_\_\_\_ (tell her you will keep her name and number and call her back in a month or two).

*If yes...*

That's wonderful. We can schedule an appointment now if you'd like.  
(Schedule appointment).

---

Appointment date and time

Now, I'd like to collect some more information...

Name: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Home Tele. # (\_\_\_\_) \_\_\_\_\_ Work Tele. # (\_\_\_\_) \_\_\_\_\_

Date of Birth: \_\_\_\_\_

Referral Sources:

(1) \_\_\_\_\_ Self

(A) \_\_\_\_\_ Fact Sheet

(B) \_\_\_\_\_ Newspaper Article

(C) \_\_\_\_\_ Refused or Ineligible - Tamoxifen

(D) \_\_\_\_\_ Called FCCC and was referred

(E) \_\_\_\_\_ Other \_\_\_\_\_

(2) \_\_\_\_\_ Physician \_\_\_\_\_

(3) \_\_\_\_\_ Hospital \_\_\_\_\_

(4) \_\_\_\_\_ Patient \_\_\_\_\_

(5) \_\_\_\_\_ C.I.S. \_\_\_\_\_

(6) \_\_\_\_\_ Relative a participant \_\_\_\_\_

(7) \_\_\_\_\_ Friend a participant \_\_\_\_\_

(8) \_\_\_\_\_ A friend told her about program \_\_\_\_\_

(5) \_\_\_\_\_ Other \_\_\_\_\_

*For Accruals Only*

Gail Model Information:

\_\_\_\_\_ Age

\_\_\_\_\_ Age at Menarche

\_\_\_\_\_ # of Breast Biopsies

If yes, do you know the diagnosis? \_\_\_\_\_

\_\_\_\_\_ Age of First Pregnancy

\_\_\_\_\_ # of FDRs with Breast Cancer

Do you have any questions? You will be receiving the questionnaire within the next week. I will give you my telephone number in case you have any questions. It is <phone number>. Please try and come in a half an hour early for your appointment because we would like to go over the family history part of your questionnaire with you. I will be sending you a confirmation letter and directions to <Network hospital>. Feel free to call me with any questions. I will be talking to you soon. Thanks again!

*For office use only*

ID # \_\_\_\_\_

MR # \_\_\_\_\_

Initial Visit \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

MM/DD/YY

## **Health History Questionnaire**

### **Family Risk Assessment**

This questionnaire has been developed by the Fox Chase Cancer Center in conjunction with the Fox Chase Network to collect information about your family history and your personal health. This information will help us identify medical or family history information that is important in understanding cancers that may run in a family. Participation is voluntary and you can withdraw at any time. All the information that you provide will be kept confidential. A code number will be used to track any information and your name will not be used. If you do participate, you will receive a family tree called a pedigree and feedback about your family history. Your participation will benefit you and your family by helping you better understand your risk for cancer. Please sign below, if you agree to participate in this Family Risk Assessment. Thank you.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

### **Section A -- Personal History**

Name: \_\_\_\_\_

(first)

(middle)

(last)

\_\_\_\_\_  
(street)

Address: \_\_\_\_\_

(city)

(state)

(zip)

Telephone:    **Home** (    ) \_\_\_\_\_    **Work** (    ) \_\_\_\_\_

1. What is your race or ethnic background?

1 ☐ White

2 ☐ Black

3 ☐ Hispanic

4 ☐ Asian

5 ☐ Other \_\_\_\_\_

2. What is the highest level of schooling you've completed?

1 ☐ Grade school

2 ☐ High school/G.E.D.

3 ☐ College

4 ☐ Post graduate

3. Which of the following describes your current marital situation?

1 ☐ Never married

2 ☐ Married or living as married

3 ☐ Divorced or separated

4 ☐ Widowed

## SECTION B -- FAMILY HISTORY OF CANCER

### *Part 1 -- You, Your Spouse, Your Parents and Your Grandparents*

- Fill in the full name, "Date of Birth" and "Date of Death" (where applicable) of each family member. Include only blood relatives and spouse. Do not include adoptive, foster or step- parents or grandparents. Circle "A" if the relative is alive and "D" if the relative is deceased.
- For each relative, circle whether or not they have had cancer. (Circle Yes or No). If you are not certain, circle "?" and fill in whatever information you can. **The shaded areas should only be completed for those relatives who have had cancer.**
- For those who have had cancer, fill in what type of cancer they have had -- "Type of Cancer," and about how old they were when they were told they had cancer "Age at Diagnosis." When possible, name the hospital where the cancer was treated and, if deceased, the place "City and State" of death.
- **If you are not certain of some dates of birth or dates of death, please estimate the year and circle those that are estimates.**

	First & Last Name	Date of Birth MM/DD/YY	Alive(A) Deceased(D) (circle)	Date of Death MM/DD/YY	Has had Cancer (circle)	Type of Cancer	Age at Diagnosis	Hospital Cancer was Treated	Place "City & State" of Death
1	Yourself	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
2	Your Mother	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
3	Mother's Mother	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
4	Mother's Father	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
5	Your Father	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
6	Father's Mother	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
7	Father's Father	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
8	Spouse	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
9	_____	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
10	_____	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____



## SECTION B -- FAMILY HISTORY OF CANCER

### *Part 2 -- Your Brothers and Sisters*

- Fill in the full names, "Date of Birth" and "Date of Death" (where applicable) of your brothers and sisters. Include only blood relatives. Do not include adoptive, foster or step-brothers or sisters. Circle "B" for brother and "S" for sister. Include their "Date of Birth" and circle "A" if the relative is alive and "D" if the relative is deceased.
- For each relative, circle whether or not they have had cancer. (Circle Yes or No). If you are not certain, circle "?" and fill in whatever information you can. **The shaded areas should only be completed for those relatives who have had cancer.**
- For those who have had cancer, fill in what type of cancer they have had -- "Type of Cancer," and about how old they were when they were told they had cancer "Age at Diagnosis." When possible, name the hospital where the cancer was treated and, if deceased, the place "City and State" of death.
- **If you are not certain of some dates of birth or dates of death, please estimate the year and circle those that are estimates.**

☐ Check here if you have no brothers or sisters.

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only

First & Last Name	Brother or Sister	Date of Birth MM/DD/YY	Alive(A) Deceased(D) (circle)	Date of Death MM/DD/YY	Has had Cancer (circle)	Type of Cancer	Age at Diagnosis	Hospital Cancer was Treated	Place "City & State" of Death	
11 _____	B S	___/___/___	A D	___/___/___	Yes No ?					HM HF
12 _____	B S	___/___/___	A D	___/___/___	Yes No ?					
13 _____	B S	___/___/___	A D	___/___/___	Yes No ?					
14 _____	B S	___/___/___	A D	___/___/___	Yes No ?					
15 _____	B S	___/___/___	A D	___/___/___	Yes No ?					
16 _____	B S	___/___/___	A D	___/___/___	Yes No ?					

## SECTION B -- FAMILY HISTORY OF CANCER

### Part 3 -- Your Children

- Fill in the names, "Date of Birth" and "Date of Death" (where applicable) of your children. Include only blood relatives. Do not include adoptive, foster or step-children. Circle "S" for son and "D" for daughter. Circle "A" if the relative is alive and "D" if the relative is deceased.
- For each relative, circle whether or not they have had cancer. (Circle Yes or No). If you are not certain, circle "?" and fill in whatever information you can. **The shaded areas should only be completed for those relatives who have had cancer.**
- For those who have had cancer, fill in what type of cancer they have had -- "Type of Cancer," and about how old they were when they were told they had cancer "Age at Diagnosis." When possible, name the hospital where the cancer was treated and, if deceased, the place "City and State" of death.
- \* If you are not certain of some dates of birth or dates of death, please estimate the year and circle those that are estimates.

☐ Check here if you have no biological children.

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17	First & Last Name	Son or Daughter	Date of Birth MM/DD/YY	Alive(A) Deceased(D) (circle)	Date of Death MM/DD/YY	Has Had Cancer (circle)	Type of Cancer	Age at Diagnosis	Hospital Cancer was Treated	Place "City & State" of Death
		S D	___/___/___	A D	___/___/___	Yes No ?				
		S D	___/___/___	A D	___/___/___	Yes No ?				
		S D	___/___/___	A D	___/___/___	Yes No ?				
		S D	___/___/___	A D	___/___/___	Yes No ?				
		S D	___/___/___	A D	___/___/___	Yes No ?				
		S D	___/___/___	A D	___/___/___	Yes No ?				
		S D	___/___/___	A D	___/___/___	Yes No ?				

## SECTION B -- FAMILY HISTORY OF CANCER

### *Part 4 -- Your Mother's Brothers and Sisters*

- Fill in the names, "Date of Birth" and "Date of Death" (where applicable) of your mother's brothers and sisters. Include only blood relatives. Do not include adoptive, foster or step- brothers or sisters. Circle "B" for brother and "S" for sister. Include their "Date of Birth" and circle "A" if the relative is alive and "D" if the relative is deceased.
- For each relative, circle whether or not they have had cancer. (Circle Yes or No). If you are not certain, circle "?" and fill in whatever information you can. **The shaded areas should only be completed for those relatives who have had cancer.**
- For those who have had cancer, fill in what type of cancer they have had -- "Type of Cancer," and about how old they were when they were told they had cancer "Age at Diagnosis." When possible, name the hospital where the cancer was treated and, if deceased, the place "City and State" of death.
- **If you are not certain of some dates of birth or dates of death, please estimate the year and circle those that are estimates.**

☐ Check here if your mother had no brothers or sisters.

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First & Last Name	Brother or Sister	Date of Birth MM/DD/YY	Alive(A) Deceased(D) (circle)	Date of Death MM/DD/YY	Has had Cancer (circle)	Type of Cancer	Age at Diagnosis	Hospital Cancer was Treated	Place "City & State" of Death	office use only	
										HM	HF
23 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____	_____	_____
24 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____	_____	_____
25 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____	_____	_____
26 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____	_____	_____
27 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____	_____	_____
28 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____	_____	_____

## SECTION B -- FAMILY HISTORY OF CANCER

### *Part 5 -- Your Father's Brothers and Sisters*

- Fill in the names, "Date of Birth" and "Date of Death" (where applicable) of your father's brothers and sisters. Include only blood relatives. Do not include adoptive, foster or step- brothers or sisters. Circle "B" for brother and "S" for sister. Include their "Date of Birth" and circle "A" if the relative is alive and "D" if the relative is deceased.
- For each relative, circle whether or not they have had cancer. (Circle Yes or No). If you are not certain, circle "?" and fill in whatever information you can. **The shaded areas should only be completed for those relatives who have had cancer.**
- For those who have had cancer, fill in what type of cancer they have had -- "Type of Cancer," and about how old they were when they were told they had cancer "Age at Diagnosis." When possible, name the hospital where the cancer was treated and, if deceased, the place "City and State" of death.
- \* If you are not certain of some dates of birth or dates of death, please estimate the year and circle those that are estimates.

☐ Check here if your father had no brothers or sisters.

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First & Last Name	Brother or Sister	Date of Birth MM/DD/YY	Alive(A) Deceased(D) (circle)	Date of Death MM/DD/YY	Has had Cancer (circle)	Type of Cancer	Age at Diagnosis	Hospital Cancer was Treated	Place "City & State" of Death
29 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
30 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
31 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
32 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
33 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____
34 _____	B S	___/___/___	A D	___/___/___	Yes No ?	_____	_____	_____	_____

HIM  
HF

## SECTION B -- FAMILY HISTORY OF CANCER

### Part 6 -- Additional Family Members

- Please use this page to add any additional blood relations, such as first cousins, grandchildren, nieces or nephews who you think should be included in your family history.
- Fill in the name, "Date of Birth" and "Date of Death" (where applicable) of each relative. Include only blood relatives. Do not include adoptive, foster or step- relatives. Circle 'M' for male and 'F' for female. Circle "A" if the relative is alive and "D" if the relative is deceased.
- For each relative, circle whether or not they have had cancer. (Circle Yes or No). If you are not certain, circle "?" and fill in whatever information you can. **The shaded areas should only be completed for those relatives who have had cancer.**
- For those who have had cancer, fill in what type of cancer they have had -- "Type of Cancer," and about how old they were when they were told they had cancer "Age at Diagnosis." When possible, name the hospital where the cancer was treated and, if deceased, the place "City and State" of death.
- **If you are not certain of some dates of birth or dates of death, please estimate the year and circle those that are estimates.**

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First & Last Name	Relationship	Male or Female (circle 1)	Date of Birth MM/DD/YY	Alive(A) Deceased(D) (circle)	Date of Death MM/DD/YY	Has had Cancer (circle)	Type of Cancer	Age at Diagnosis	Hospital Cancer was Treated	Place "City & State" of Death	
35		M F	___/___/___	A D	___/___/___	Yes No ?					
36		M F	___/___/___	A D	___/___/___	Yes No ?					
37		M F	___/___/___	A D	___/___/___	Yes No ?					
38		M F	___/___/___	A D	___/___/___	Yes No ?					
39		M F	___/___/___	A D	___/___/___	Yes No ?					
40		M F	___/___/___	A D	___/___/___	Yes No ?					

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#

## Section C -- Reproductive History

1. How old were you when your periods began? (\_\_\_\_) Years old
2. Do you currently have menstrual periods?
  - 1 ☐ Yes *SKIP TO Q.5*
  - 2 ☐ No *CONTINUE*
3. If you are not still menstruating, how old were you when your periods stopped?  
(\_\_\_\_) Years old
4. If you are not still menstruating, why did your periods stop?
  - 1 ☐ Natural menopause
  - 2 ☐ Surgical hysterectomy
  - 3 ☐ Other \_\_\_\_\_
5. How many live born children have you had? (\_\_\_\_)
  - a. With how many of your children did you breast-feed? (\_\_\_\_)
  - b. In your lifetime, for how many total months did you breast-feed? (\_\_\_\_) months
6. How many miscarriages have you had? (\_\_\_\_)
7. How many terminated pregnancies (abortions) have you had? (\_\_\_\_)
8. How old were you when your first child was born?  
(\_\_\_\_) Years old
9. In your opinion, have you ever had any problems in getting pregnant?
  - 1 ☐ Yes *CONTINUE*
  - 2 ☐ No *SKIP TO Q.10*
  - 8 ☐ Don't Know *SKIP TO Q.10*

a. If yes, how long did it take you to get pregnant? (\_\_\_\_) Years

☐ Never got pregnant

b. Have you ever consulted a doctor about difficulty in getting pregnant?

1 ☐ Yes

2 ☐ No

c. If yes, what was the diagnosis of the problem?

DIAGNOSIS \_\_\_\_\_

10. Have you ever taken Clomid (Clomiphene) or Pergonal to induce ovulation?

1 ☐ Yes *CONTINUE*

2 ☐ No *SKIP TO Q.11*

a. For how many months was Clomid used?

1 ☐ 0 months

4 ☐ 4-5

2 ☐ 1

5 ☐ 6-11

3 ☐ 2-3

6 ☐ 12+ months

b. For how many months was Pergonal used?

1 ☐ 0 months

4 ☐ 4-5

2 ☐ 1

5 ☐ 6-11

3 ☐ 2-3

6 ☐ 12+ months

11. Have you ever used birth control pills?

1 ☐ Yes *CONTINUE*

2 ☐ No *SKIP TO Q.12*

a. If yes, how old were you when you started taking them? \_\_\_\_\_ years

b. If yes, for how many years did you use them? \_\_\_\_\_ years

12. Have you ever used hormone replacement medication (for example: Premarin)?

1 ☐ Yes *CONTINUE*

2 ☐ No *SKIP TO SECTION D*

8 ☐ Don't know *SKIP TO SECTION D*

a. If yes, for how many years did you use them? \_\_\_\_\_ years

## Section D -- Exposures

1. Have you ever used products which contain talc (e.g. dusting power with talc)?

1 ☐ Yes  
2 ☐ No  
8 ☐ Don't know

2. Were you ever treated with a series of x-rays to the front of your neck for acne, neck tumor or any other reason? (This does not include routine screening x-rays like, dental, chest or mammograms).

1 ☐ Yes  
2 ☐ No

3. How many alcoholic drinks do you consume per day?

1 ☐ None/Rarely  
2 ☐ 0 - 1 per day  
3 ☐ 2 per day  
4 ☐ 3 - 4 per day  
5 ☐ Greater than 4 per day

4. Have YOU smoked a cigarette, even a puff in the past 30 days?

1 ☐ Yes **GO TO PART 2**  
2 ☐ No **(CONTINUE)**

5. Have you smoked 100 cigarettes in your lifetime? That's about 5 packs.

1 ☐ Yes **GO TO PART 1 BELOW**  
2 ☐ No **SKIP TO SECTION E**

### PART 1 -- FOR FORMER CIGARETTE SMOKERS ONLY

6. About how old were you when you first started smoking at least one cigarette per day? (\_\_\_\_) years old
7. When you were smoking regularly, how many cigarettes did you smoke on a typical day? (\_\_\_\_) cigarettes not packs per day



8. About how old were you when you last quit smoking? (\_\_\_\_) years old
9. For how many years did you smoke regularly, at least one cigarette a day? (\_\_\_\_) years

**SKIP TO SECTION E IF YOU COMPLETED PART 1 ABOVE**

**PART 2 -- FOR CURRENT CIGARETTE SMOKERS ONLY**

10. About how old were you when you first started smoking at least one cigarette a day? (\_\_\_\_) years old
11. For how many years have you smoked regularly, at least one cigarette a day? (\_\_\_\_) years
12. Since you started smoking regularly, about how many cigarettes do you smoke on a typical day? (\_\_\_\_) cigarettes  
not packs per day
13. During the past 7 days, how many cigarettes did you smoke on a typical day? (\_\_\_\_) cigarettes  
not packs per day
14. Do you smoke your first cigarette during the first half hour (30 minutes) after you wake up?

- 1 ☐ Yes  
2 ☐ No

## Section E -- Personal Medical History

1. What is your weight now? \_\_\_\_\_ lbs.
2. What is your height now? \_\_\_\_\_ ft./in.
3. Have you ever had any of the following medical conditions? (*CIRCLE YES=1, NO=2, DON'T KNOW=8*)

	<u>YES</u>	<u>NO</u>	<u>DON'T KNOW</u>
Endometriosis	1	2	8
Cysts on the ovaries	1	2	8
Fibrocystic breast disease	1	2	8
Rectal/colon polyps	1	2	8
Ulcerative colitis	1	2	8
Abnormal pap smear	1	2	8

4. Please list any medicine you take on a regular basis. Please include prescription and non-prescription drugs as well as vitamins.

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5. Have you ever had a breast biopsy (that is when a sample of breast tissue is taken and examined for abnormalities)?

- 1 ☐ Yes **CONTINUE**  
 2 ☐ No **SKIP TO Q.6**  
 8 ☐ Don't know **SKIP TO Q.6**

a. If yes, how many breast biopsies have you had? \_\_\_\_\_ biopsies

6. Have you ever **considered** having your breasts surgically removed to prevent breast cancer? (This is called prophylactic mastectomy).

- 1 ☐ Yes  
 2 ☐ No

7. Have either or both of your breasts been removed?

- 1 ☐ Yes
  - a ☐ one *CONTINUE*
  - b ☐ both *CONTINUE*
- 2 ☐ No *GO TO Q.8*

a. If yes, why did you have your breast(s) removed?

- 1 ☐ I had breast cancer
- 2 ☐ To prevent my developing breast cancer
- 3 ☐ Other \_\_\_\_\_

8. Have you ever **considered** having your ovaries surgically removed to prevent ovarian cancer? (This is called prophylactic oophorectomy).

- 1 ☐ Yes
- 2 ☐ No

9. Have you ever had a hysterectomy (surgical removal of the uterus)?

- 1 ☐ Yes *CONTINUE*
- 2 ☐ No *CONTINUE*
- 8 ☐ Don't know *CONTINUE*

a. If yes, how old were you? (\_\_\_\_) years

10. Have either or both of your ovaries been surgically removed?

- 1 ☐ Yes *CONTINUE*
  - a ☐ both
  - b ☐ one
- 2 ☐ No *SKIP TO SECTION F*
- 8 ☐ Don't know *SKIP TO SECTION F*

a. If yes, how old were you? (\_\_\_\_) years

b. If yes, why did you have your ovaries removed?

- 1 ☐ I had ovarian cancer
- 2 ☐ To prevent my developing ovarian cancer
- 3 ☐ Other \_\_\_\_\_

## Section F -- General Medical Care

1. Have you ever had a mammogram (an x-ray of the breasts)?

1 ☐ Yes *CONTINUE*  
2 ☐ No *SKIP TO Q.2*

- a. If yes, how old were you when you had your first mammogram?

\_\_\_\_\_ years

- b. If yes, how many mammograms have you had in the past 5 years?

\_\_\_\_\_ mammograms

- c. When was the last time you had a mammogram? \_\_\_\_\_ (approximately)  
Mo/Yr

- d. Have you ever been told that a mammogram you had was abnormal?

1 ☐ Yes  
2 ☐ No

2. During the past 6 months, about how often did you examine your own breasts for lumps or other changes?

\_\_\_\_\_ times

3. When did a physician or a health care practitioner last examine your breasts?

1 ☐ Within the past year  
2 ☐ Between one and three years ago  
3 ☐ More than three years ago  
4 ☐ Never

4. Have you ever had a Pap smear?

1 ☐ Yes *CONTINUE*  
2 ☐ No *SKIP TO Q.5*

- a. If yes, when was the last time you had a Pap smear?

\_\_\_\_\_ (approximately)  
Mo/Yr

5. Have you ever had any of the following tests to screen for ovarian cancer?

- a. Pelvic exam (examination of the cervix and uterus by a physician or health care practitioner)

- 1 ☐ Yes  
2 ☐ No  
8 ☐ Don't Know

If yes, how many pelvic exams have you had in the past 5 years? \_\_\_\_\_ exams

When was the last time you had this? \_\_\_\_\_ (approximately)  
Mo/Yr

- b. CA-125 (a blood test that is sometimes used to find ovarian cancer)

- 1 ☐ Yes  
2 ☐ No  
8 ☐ Don't know

If yes, how many CA-125 tests have you had in the past three years?

\_\_\_\_\_ years

When was the last time you had this? \_\_\_\_\_ (approximately)  
Mo/Yr

- c. Pelvic or transvaginal ultrasound

- In a pelvic ultrasound, a probe is moved over your abdomen to project sound waves and an image is displayed on a screen.
- A transvaginal ultrasound involves inserting a plastic sound probe into the vagina and an image of the ovaries is displayed on a screen.

- 1 ☐ Yes  
2 ☐ No  
8 ☐ Don't know

If yes, how many pelvic or transvaginal ultrasound exams have you had in the past five years? \_\_\_\_\_ (Don't include those done for pregnancy).

When was the last time you had this? \_\_\_\_\_ (approximately)  
Mo/Yr

6. Have you ever had a test for blood in your stool (bowel movements)?

- 1 ☐ Yes
- 2 ☐ No
- 8 ☐ Don't know

7. Have you ever had a sigmoidoscopy or a colonoscopy? (Both exams involve using a thin, lighted tube to examine the colon and rectum).

- 1 ☐ Yes
- 2 ☐ No
- 8 ☐ Don't know

*The next three questions ask your opinion about your chances of getting cancer someday.*

8. In your opinion, what are your chances of getting breast cancer someday?

- 1 ☐ Much more than the average woman
- 2 ☐ More than the average woman
- 3 ☐ Same as the average woman
- 4 ☐ Less than the average woman
- 5 ☐ Much less than the average woman

9. In your opinion, what are your chances of getting ovarian cancer someday?

- 1 ☐ Much more than the average woman
- 2 ☐ More than the average woman
- 3 ☐ Same as the average woman
- 4 ☐ Less than the average woman
- 5 ☐ Much less than the average woman

10. In your opinion, what are your chances of getting colon cancer someday?

- 1 ☐ Much more than the average woman
- 2 ☐ More than the average woman
- 3 ☐ Same as the average woman
- 4 ☐ Less than the average woman
- 5 ☐ Much less than the average woman

11. What type of health insurance do you currently have?

- 1 ☐ Uninsured
- 2 ☐ Blue Cross/Blue Shield
- 3 ☐ Other private insurance \_\_\_\_\_
- 4 ☐ HMO. . . specify \_\_\_\_\_
- 5 ☐ Medicare
- 6 ☐ Medicaid

If you would like your doctor to be informed of our screening recommendations, please provide us with his/her name, address and telephone number below.

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Phone: (     ) \_\_\_\_\_

*Thank you*

<i>For Office Use Only</i> _____
_____
_____
_____

M.R. No.: \_\_\_\_\_  
Date: \_\_\_\_\_

The following surveys look at the different thoughts and feelings that women with a family history of cancer are experiencing. The information that you provide will help us to develop future programs for women with cancer in their families. All of the information provided in this survey will be kept completely confidential. Please date the survey in the space provided above.

Thank you very much for your help!



Below is a list of words that describe feelings people have. Please read each one carefully. Then CIRCLE ONE NUMBER to the right which best describes HOW YOU HAVE BEEN FEELING THE PAST WEEK, INCLUDING TODAY.

	<u>NOT AT ALL</u>	<u>A LITTLE</u>	<u>A FAIR AMOUNT</u>	<u>QUITE A BIT</u>	<u>EXTREMELY</u>
1. Friendly	0	1	2	3	4
2. Tense	0	1	2	3	4
3. Angry	0	1	2	3	4
4. Worn out	0	1	2	3	4
5. Unhappy	0	1	2	3	4
6. Clear-headed	0	1	2	3	4
7. Lively	0	1	2	3	4
8. Confused	0	1	2	3	4
9. Sorry for things done	0	1	2	3	4
10. Shaky	0	1	2	3	4
11. Listless	0	1	2	3	4
12. Peeved	0	1	2	3	4
13. Considerate	0	1	2	3	4
14. Sad	0	1	2	3	4
15. Active	0	1	2	3	4
16. On edge	0	1	2	3	4
17. Grouchy	0	1	2	3	4
18. Blue	0	1	2	3	4
19. Energetic	0	1	2	3	4
20. Panicky	0	1	2	3	4

		<u>NOT AT</u> <u>ALL</u>	<u>A</u> <u>LITTLE</u>	<u>A FAIR</u> <u>AMOUNT</u>	<u>QUITE</u> <u>A BIT</u>	<u>EXTREMELY</u>
21.	Hopeless	0	1	2	3	4
22.	Relaxed	0	1	2	3	4
23.	Unworthy	0	1	2	3	4
24.	Spiteful	0	1	2	3	4
25.	Sympathetic	0	1	2	3	4
26.	Uneasy	0	1	2	3	4
27.	Restless	0	1	2	3	4
28.	Unable to concentrate	0	1	2	3	4
29.	Fatigued	0	1	2	3	4
30.	Helpful	0	1	2	3	4
31.	Annoyed	0	1	2	3	4
32.	Discouraged	0	1	2	3	4
33.	Resentful	0	1	2	3	4
34.	Nervous	0	1	2	3	4
35.	Lonely	0	1	2	3	4
36.	Miserable	0	1	2	3	4
37.	Muddled	0	1	2	3	4
38.	Cheerful	0	1	2	3	4
39.	Bitter	0	1	2	3	4
40.	Exhausted	0	1	2	3	4
41.	Anxious	0	1	2	3	4
42.	Ready to fight	0	1	2	3	4
43.	Good natured	0	1	2	3	4

	<u>NOT AT ALL</u>	<u>A LITTLE</u>	<u>A FAIR AMOUNT</u>	<u>QUITE A BIT</u>	<u>EXTREMELY</u>
44. Gloomy	0	1	2	3	4
45. Desperate	0	1	2	3	4
46. Sluggish	0	1	2	3	4
47. Rebellious	0	1	2	3	4
48. Helpless	0	1	2	3	4
49. Weary	0	1	2	3	4
50. Bewildered	0	1	2	3	4
51. Alert	0	1	2	3	4
52. Deceived	0	1	2	3	4
53. Furious	0	1	2	3	4
54. Efficient	0	1	2	3	4
55. Trusting	0	1	2	3	4
56. Full of pep	0	1	2	3	4
57. Bad-tempered	0	1	2	3	4
58. Worthless	0	1	2	3	4
59. Forgetful	0	1	2	3	4
60. Carefree	0	1	2	3	4
61. Terrified	0	1	2	3	4
62. Guilty	0	1	2	3	4
63. Vigorous	0	1	2	3	4
64. Uncertain about things	0	1	2	3	4
65. Bushed	0	1	2	3	4

BE SURE YOU HAVE ANSWERED EVERY ITEM. THANK YOU FOR YOUR HELP !

Below is a set of four scenarios. For each, check ALL of the statements that might apply to you.

1. Imagine that you are afraid of the dentist and you have to go. Which of the following things would you do? Check all of the statements that might apply to you.

- ☐ I would ask the dentist exactly what he was going to do.
- ☐ I would try to think about pleasant things.
- ☐ I would want the dentist to tell me when I would feel the pain.
- ☐ I would try to sleep.
- ☐ I would watch all the dentist's movements and listen for the sound of his drill.
- ☐ I would watch the flow of water from my mouth to see if it had blood in it.
- ☐ I would do mental puzzles in my mind or daydream.
- ☐ I would take a tranquilizer or have a drink before going.

2. Imagine that you are being held hostage in a bank by a gang of robbers. Which of the following would you do? Check all of the statements that might apply to you.

- ☐ I would sit by myself and have as many daydreams and fantasies as I could.
- ☐ I would stay alert and try to keep myself from falling asleep.
- ☐ I would talk about pleasant things with other hostages.
- ☐ If there was a radio, I would stay near it and listen to reports about what the police were doing.
- ☐ I would watch every movement of the robbers and keep an eye on their weapons.
- ☐ I would try to sleep as much as possible.
- ☐ I would think about how nice it's going to be when I get home.
- ☐ I would make sure I knew where every possible exit was.

3. Imagine that, due to a large drop in sales, it is rumored that several people in your department at work will be laid off. Your supervisor has turned in an evaluation of your work for the past year. The decision about layoffs has been made and will be announced in several days. Check all of the statements that might apply to you.

\_\_\_\_\_ I would talk to my fellow workers to see if they knew anything about what the supervisor's evaluation of me said.

\_\_\_\_\_ I would review the list of duties for my present job and try to figure out if I had fulfilled them all.

\_\_\_\_\_ I would go to the movies to take my mind off things.

\_\_\_\_\_ I would try to remember any arguments or disagreements I might have had with the supervisor that would have lowered his opinion of me.

\_\_\_\_\_ I would push all thoughts of being laid off out of my mind.

\_\_\_\_\_ I would tell my spouse that I'd rather not discuss my chances of being laid off.

\_\_\_\_\_ I would continue doing my work as if nothing special was happening.

\_\_\_\_\_ I would try to think which employees in my department the supervisor might have thought had done the worst job.

4. Imagine that you are on an airplane, when the plane suddenly goes into a deep dive. After a short time, the pilot announces that nothing is wrong, although the rest of the ride may be rough. You are worried that something may be wrong. Check all of the statements that might apply to you.

\_\_\_\_\_ I would carefully read the information about safety features in the plan and make sure I knew where the emergency exists were.

\_\_\_\_\_ I would make small talk with the person beside me.

\_\_\_\_\_ I would watch the end of the movie, even if I had seen it before.

\_\_\_\_\_ I would call for the stewardess and ask her exactly what the problem was.

\_\_\_\_\_ I would listen carefully to the engine for unusual noises and would watch the crew to see if they were acting strangely.

\_\_\_\_\_ I would talk to the passengers beside me about what might be wrong.

\_\_\_\_\_ I would settle down and read a book or magazine or write a letter.

\_\_\_\_\_ I would order a drink or tranquilizer from the stewardess.

Below is a list of comments made by people after they learn that cancer runs in their families. Please circle each item, indicating how frequently these comments were true for you DURING THE PAST SEVEN DAYS. If they did not occur during that time, please circle in the "not at all" column.

	Not at all	Rarely	Some- times	Often
1. I thought about it when I didn't mean to.	0	1	3	5
2. I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	3	5
3. I tried to remove it from memory.	0	1	3	5
4. I had trouble falling asleep or staying asleep, because of pictures or thoughts about it that came into my mind.	0	1	3	5
5. I had waves of strong feelings about it.	0	1	3	5
6. I had dreams about it.	0	1	3	5
7. I stayed away from reminders of it.	0	1	3	5
8. I felt as if it hadn't happened or it wasn't real.	0	1	3	5
9. I tried not to talk about it.	0	1	3	5
10. Pictures about it popped into my mind.	0	1	3	5
11. Other things kept making me think about it.	0	1	3	5
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	3	5
13. I tried not to think about it.	0	1	3	5
14. Any reminder brought back feelings about it.	0	1	3	5
15. My feelings about it were kind of dumb.	0	1	3	5

from Horowitz et al (1979)

THANKS FOR YOUR HELP!

## Standard Letter to confirm appointment for Education Session

<Network Staff>

<Network Address 1>

<Network Address 2>

<date>

<Name>

<Address 1>

<Address 2>

Dear <Name>

I would like to confirm <date> at <time> as the date for the Breast Cancer Risk Education session (*adapt name to individual Network Hospital program name*). If possible try to arrive about on half hour early to process the necessary paper work. Enclosed are directions to <Network hospital> *Add any other directions of where you will meet.*

I have also enclosed a set of questionnaires for you to fill out. The Health History Questionnaire will provide us with information about your personal and family history of cancer. With information from this questionnaire we will be able to give you:

- a family pedigree - this is a type of family tree that looks at the history of cancer in several generations
- feedback about your family history and your own personal risk for cancer.

The other questionnaires will help us to better address the different thoughts and feelings that women with a family history may be experiencing. All the information provided on the questionnaires will ne kept completely confidential. A code number will be used to track any information and your name will nor be used. Please complete these questionnaires as best you can and bring them with you to the education session.

Should you have any questions, please call me <Network Staff> at <phone>. Thank you very much.

Sincerely,

## **Group Educational Session**

### **Prior to Session:**

- \* Have ready:
  1. flip chart or slides for educational session
  2. Folders made up for each participant
  3. Pens or pencils
  4. Dorlands, if your Network Hospital has opted to send letter and screening recommendations to the participant's primary care provider.
- \* Meet with women in <designate area> at <designated time>, preferably 15 to 30 minutes before session.
- \* Collect and go over the Health History Questionnaire with each participant
- \* Check for date of birth, half and full siblings, father #'s, additional relative information and missing data. (see Health History Instructions)
- \* Write in dates of session on Health History Questionnaire (HHQ).
- \* Make sure to collect the Health History Questionnaire and put into individual folders.
- \* Bring woman to assigned room.

### **During the Session (if there is a second person to help):**

- \* Keep all "No shows" aside and mark on telephone survey. (call for new session)
- \* Go through HHQ's to ensure all information is up to date.
- \* Check the last page of HHQ for physician information. Look in Dorlands to complete address and telephone number if available.
- \* Copy the physicians name, address, and telephone number on both the participants form (in participant's packet) and the physician letter (so individual letters can be done at the end)
- \* On participant letter try to write the woman's age and date of last mammogram (time permitting). This will help to "quicken" the letter writing process at the end of the session.
- \* Put patient packets aside so can be passed out at end of session.
- \* For those network facilities using the Gail Model Scores, pass out sheets when facilitator is ready.



## At The End Of The Session:

- \* Have packets ready for distribution that would include:
  1. Interest checklist form - this form will ask about interest in
    - a. participating in an individualized risk assessment session
    - b. having a letter sent to their physician with recommendation for screening.  
(*This form is signed by participant and serves as a consent to send a letter to their primary care providers.*)
  2. Sheet with <Network Staff> phone number to call for making appt. for individual risk assessment session.
  3. An Billing information <Billing decisions made by each Network Institution>
- \* Give out packets to each individual.
- \* Tell them that we would like to send a letter of recommendations to their physician. If they would like this done, please check yes and sign their name on Interest Sheet.  
If they have not given physician's name, address and telephone number on HHQ, they can now write in their Doctor's name. (some may have already done this)
- \* We will also mail them a letter of screening recommendation and enclose family pedigree.
- \* Explain Individual Risk Assessment process.
  1. Give times that you are available to meet
  2. Explain that they will receive (at that Session)
    - a. pedigree expansion - will go over pedigree and expand the family information
    - b. preliminary information about the family pattern of cancer
  3. After the session - the pedigree information is reviewed by the FCCC Pedigree Review Committee here appropriate families are identified for genetic studies.
  4. Make sure that it is clear that genetic studies are not appropriate for everyone and that this is a process that can take weeks or months. Genetic studies are still research and not a diagnostic test
- \* Tell them they can be involved with the High Risk Registry program in a variety of ways and there is no obligation.
  1. Some women come only to the education session and give their HHQ
  2. Some women will go one for the risk assessment but opt not to have genetic testing
  3. Some women have the risk assessment and the genetic testing.
- \* If they would like to make an appointment they should contact <Network Staff> designated.

**Following Session:**

- \* Complete letters to participants and physicians.
- \* You will need to write in the physician's addresses for those who were incomplete.
- \* The next day, HHQs need to be sent to Fox Chase Cancer Center for data entry and generation of family pedigree. (Count 3 week complete turn around time)
- \* When pedigrees are returned, you are ready to do individualized risk assessment session.

## HEALTH HISTORY INSTRUCTIONS

- I. Review entire HHQ for missing data while participant/patient is filling out the psychological measures.
- II. Section B. Review each page with participant/patient to fill in missing data. Pay particular attention to Alive, Deceased. Ask if any dates are estimates, if yes, circle.

Part 2: Ask if any siblings have a different parent than the participant. If yes, ask which is the common parent. If mother, write HM (for half sibling by mother) in the *"office use only"* column next to the appropriate siblings. Write HF for half siblings by the father.

Part 3: Ask if the children are all fathered by the spouse named in Part 1. If not, use lines 9 and 10 of Part 1 to fill in the names of the man or men who have fathered the children. Collect information on date of birth, cancer, etc., if available. Write the corresponding father's number in the *"office use only"* column for the appropriate child on Part 3.

Example: If children 17 and 18 are fathered by a man other than #8 on Part 1, fill in the father's name on line 9, Part 1. Write #9 in *"office use only"* for children 17 and 18 on Part 3.

Part 4: Ask if the participant's mother and her siblings have the same parents. If some are half siblings fill in HM for half by mother or HF for half by father in *"office use only"* column.

Part 5: Same as Part 4, but for father's siblings.

Part 6: If the participant lists additional relatives, ask how they are related to the participant. Write the number of the corresponding relative that connects the two in *"office use only"* column in Part 6.

Example: If #35 and #36 are cousins and related to the participant through her mother's sister #24, write 24 in the *"office use only"* column in Part 6. If #37 is a niece through participants brother #14, write 14 in the *"office use only"* column in Part 6.

- \*\* Use lines at bottom of page as needed. If the participant uses Part 6 for relatives that spill over from other sections (i.e., siblings, children, aunts or uncles), note on bottom of the corresponding page that these additional relatives are listed in Part 6. For example, if she has more siblings listed on Part 6, make a note of this on the bottom of Part 2.

<cbs/hlth/instruc>

**< Network Hospital >  
Family Risk Assessment**

Date: \_\_\_\_\_

Name: \_\_\_\_\_

—

Please check below if you are interested in scheduling an individual appointment to get feedback about your family history and risk for cancer.

\_\_\_\_\_ I am interested

\_\_\_\_\_ I am not sure

\_\_\_\_\_ I am not interested at this time

Please check below if you would like us to send a letter to your physician or primary care provider to let them know you have attended this Family Risk Assessment Education session.

\_\_\_\_\_ Yes, I would like my physician to receive a letter and to be informed that I have attended this education session.

\_\_\_\_\_ No, I do not want my physician informed.

We have recently seen your patient, , in our Family Risk Assessment Program here at the Fox Chase Cancer Center. She was referred to our program because of a family history of breast cancer. Because of her family history, we have conducted an extensive educational program including information with regards to risk factors for the development of the disease, as well as preventive measures and screening modalities. Using the Gail model, we have estimated her risk for breast cancer to be \_\_\_\_%, \_\_\_\_ times that of the average woman her age.

Our screening recommendations for women at her risk level are:

- Mammogram and clinical breast exam annually.

OR

- Because of her young age, our mammogram recommendation will depend on the results of the clinical breast exam.
- Breast self examination on a monthly basis.
- Yearly pelvic exam with pap smear and stool hemoccult.

OR

- Pelvic exam at six-month intervals with baseline transvaginal ultrasound and CA 125. If normal, the CA 125 and ultrasound can then alternate at six-month intervals.

We are in the process of developing guidelines for genetic testing for families with a history of breast cancer.

The patient is interested in the Tamoxifen Chemoprevention Trial which will soon be open. We think she may be a good candidate for the study and will evaluate her for eligibility.

Please contact us with any questions or concerns regarding these recommendations. We hope that you will find these guidelines helpful while caring for .

Sincerely yours,

Mary B. Daly, M.D., Ph.D.

MBD/jam

*By. pr. for. etc.*

Thank you for your participation in the Family Risk Assessment Program educational session. We appreciate your willingness to share your experiences with us so we can all learn more about this disease. As you know, this program is still in its developmental phases and any feedback from you would be welcomed.

The following is a list of recommendations for future screening. Because of the frequent association between breast and other cancers you will find recommendations for other diseases included as well.

- Yearly mammogram and clinical breast exam.
  - Breast self examination on a monthly basis. We can show you a very effective method for examining your breasts.
  - Yearly pelvic exam with pap smear and stool hemoccult.
- OR
- Pelvic exam at six-month intervals with baseline transvaginal ultrasound and CA 125. The CA 125 and ultrasound can then alternate at six-month intervals.

We have mailed a letter with these recommendations to Dr. so that he may be aware of these recommendations. Also, as promised, we have enclosed a copy of your family pedigree which was compiled with the information which you provided on the family history form.

As we discussed with you, the Tamoxifen Chemoprevention Trial will soon be open for enrollment if you are interested.

Thank you again for your continued participation in our program and we look forward to hearing from you with any questions or comments. If you would like to schedule a clinic visit, please call Kathleen Gillespie at (215)-728-2683. We will be glad to discuss the options for genetic testing with you at that time.

Sincerely yours,

Mary B. Daly, M.D., Ph.D.

MBD/jam  
Enclosure

*Dr. pt. form.*

Thank you for your participation in the Family Risk Assessment Program educational session. We appreciate your willingness to share your experiences with us so we can all learn more about this disease. As you know, this program is still in its developmental phases and any feedback from you would be welcomed.

The following is a list of recommendations for future screening. Because of the frequent association between ovarian and other cancers, you will find recommendations for other diseases included as well.

- Pelvic exam every six-months. Baseline CA 125 and transvaginal ultrasound. If normal, the CA 125 and ultrasound can alternate at six-month intervals.
- Yearly mammogram and clinical breast exam.
- Breast self-examination on a monthly basis. We can show you a very effective method for examining your breasts.
- Stool hemoccult for blood once a year.

We have mailed a letter with these recommendations to Dr. so that he/she may be aware of these recommendations. Also, as promised, we have enclosed a copy of your family pedigree which was compiled with the information which you provided on the family history form.

Thank you again for your continued participation in our program. We look forward to hearing from you with any questions or comments. If you would like to schedule a clinic visit, please call Kathleen Gillespie at (215) 728-2683. We will be glad to discuss the options for genetic testing with you at that time.

Sincerely yours,

Mary B. Daly, M.D., Ph.D.

MBD/jam

*Dr. Daly*

We have recently seen your patient, , in our Family Risk Assessment Program here at the Fox Chase Cancer Center. She was referred to our program because of a family history of ovarian carcinoma. Because of her family history we have conducted an extensive education program. This program includes information with regards to risk factors for the development of the disease, as well as preventive measures and screening modalities.

While we realize there are no standard guidelines for ovarian cancer screening, we think that this high risk group of women is an ideal population in which to study the effectiveness of the currently available tests. We are using the protocol which includes ovarian as well as breast and colon cancer screening. Based upon this we recommend the following:

- Pelvic exam every six months. Baseline CA 125 and transvaginal ultrasound. If normal at baseline, the CA 125 and ultrasound can alternate at six-month intervals.
- Mammogram and clinical breast exam annually.
- Breast self-examination on a monthly basis.
- Stool hemoccult annually.

We are currently in the process of developing guidelines for genetic testing for families with a history of ovarian cancer.

Please contact us with any questions or concerns regarding these recommendations. We hope that you will find these guidelines helpful while caring for .

Sincerely yours,

Mary B. Daly, M.D., Ph.D.

MBD/jam



## Breast Cancer Screening Recommendations

The following screening recommendations are made for women with a family history of breast cancer in a first or second degree relative. For clients with a family history of early onset breast cancers, initiation of screening is recommended 10 years earlier than the earliest age of onset of a first or second degree relative.

Screening Procedure	Frequency	Comments/Familial Risk Category
Breast self-exam (BSE)	Monthly from age 20.	<p><u>Site specific Breast Cancer</u></p> <ul style="list-style-type: none"> <li>◆ Breast cancer at any age with first degree relative (FDR) or 2 or more second degree relatives.</li> </ul> <p><u>Hereditary Breast and Ovarian Cancer</u></p> <ul style="list-style-type: none"> <li>◆ Ovarian cancer at any age, with a FDR with ovarian cancer at any age, or a first degree relative with breast cancer before 50 years.</li> <li>◆ Relative with primary breast and ovarian cancers.</li> <li>◆ Sister pair both with breast or ovarian cancer.</li> </ul>
Clinical Breast Examination (CBE)	<p>CBE every 6 to 12 months depending on physical findings and quality of mammograms.</p> <p>May recommend CBE every 6 months for women with dense breasts and non-revealing mammograms or for women with heightened anxiety due to risk.</p>	
Mammography	<p>For women under 35 years, initiation of mammography is recommended 10 years earlier than earliest onset of breast cancer, then repeat annually depending on quality.</p> <p>Annually for women 35 and over.</p> <p>For suspicious findings not referred for ultrasound, repeat in 6 months.</p>	

## Ovarian Cancer Screening Recommendations

The following screening recommendations are made for women with a family history of ovarian cancer in at least one first degree relative, two or more second degree relatives or a family history of ovarian cancer and multiple cancer, i.e., breast, colon, or other Lynch II cancers (See colon cancer screening recommendations). In early onset ovarian cancers, initiation of screening is recommended 10 years earlier than the earliest age of onset.

Screening Procedure	Frequency	Comments/Familial Risk Category
Pelvic Examination	At baseline and then repeat every 6 months	<p><u>Site Specific Ovarian Cancer</u></p> <ul style="list-style-type: none"> <li>♦ Ovarian cancer at any age with a first degree relative (FDR) or 2 or more second degree relatives.</li> <li>♦ Having at least one affected FDR increases the life-time risk (OR = 3.6)</li> </ul>
CA -125	<p>At baseline, repeat in 6 months and then annually to alternate with transvaginal ultrasound</p> <ul style="list-style-type: none"> <li>♦ Normal range: 8-35 U/ml</li> <li>♦ Elevation &gt;35 U/ml rule out pregnancy, endometriosis, or other cancer. If no other cause, repeat in 2 to 3 months.</li> <li>♦ Transvaginal ultrasound with two successive elevated levels.</li> </ul>	<p><u>Hereditary Breast and Ovarian Cancer</u></p> <ul style="list-style-type: none"> <li>♦ Ovarian cancer at any age, with a FDR with ovarian cancer at any age, or a first degree relative with breast cancer before 50 years.</li> <li>♦ Relative with primary breast and ovarian cancers.</li> <li>♦ Sister pair both with breast or ovarian cancer.</li> </ul>
Transvaginal Ultrasound with combination of pulsed Doppler	<p>At baseline and then repeat annually.</p> <ul style="list-style-type: none"> <li>♦ Premenopausal women are scheduled during the follicular phase of the menstrual cycle.</li> <li>♦ Repeat scanning if questionable.</li> <li>♦ Surgical exploration if suspicious.</li> </ul>	<p><u>Ovarian Cancer with HNPCC or Lynch II</u></p> <ul style="list-style-type: none"> <li>♦ Ovarian cancer approximately 20 years earlier than general population.</li> <li>♦ Family clustering of ovarian, colon, endometrial, small bowel, stomach, pancreas, and transitional cell carcinoma of ureter and renal pelvis.</li> </ul> <p><b>**Families with ovarian and HNPCC or Lynch II cancers should be referred for gastro-enterologic exam.</b></p> <p><u>Personal history of ovarian cancer</u></p> <ul style="list-style-type: none"> <li>♦ Follow screening recommendations for breast cancer</li> </ul>

## Colon Cancer Screening Recommendations

1.

Screening Procedure	Frequency	Comments/ Familial Risk Category
Fecal occult blood testing (FOBT) and digital rectal examination	<u>Average risk</u> - FOBT annually starting at age 40.	<p><u>Personal history of a sporadic breast or gynecologic cancer</u>, in the absence of family history of other malignancies.</p> <p><u>HNPCC or Lynch II</u> - "Amsterdam criteria"</p> <p>a. At least 3 relatives with history of colorectal or other cancers, especially adenocarcinomas of the endometrium, stomach, pancreas, and biliary tree, as well as transitional cell cancers of the genitourinary tract. One member of the kindred must be a first degree relative.</p> <p>b. Affected members in at least two generations</p> <p>c. At least one affected individual being &lt; 50.</p> <p>* Patients in families with HNPCC or Lynch II should be referred for gynecologic exam.</p>
Flexible sigmoidoscopy (FS)	<p><u>Average risk</u> - FS annually starting at age 50, then every 3-5 years if normal.</p> <p><u>Personal history of sporadic breast or gynecologic cancer</u> - same as the average risk, except that FS screening begins as soon as a breast or gyn cancer is diagnosed. Do not wait till 50 to begin FS.</p>	
Colonoscopy	<p><u>Hereditary Non-Polyposis Colon Cancer (HNPCC) or Lynch II (Family Cancer Syndrome)</u></p> <p>Survey all family members of an affected kindred with FOBT and rectal exam, then colonoscopy beginning at age 5 years younger than the earliest age of development of colon CA in the family or at the age of 20 if this is unknown.</p> <p>Annual colonoscopy until no adenomas, then frequency decreased to every 2-3 years.</p>	

## Colon Cancer Screening Recommendations

Screening Procedure	Frequency	Comments/Familial Risk Category
Flexible Sigmoidoscopy (FS)	<u>Familial Adenomatous Polyposis (FAP)</u> <ul style="list-style-type: none"> <li>◆ annual FS beginning at age 12 until polyps are found, then begin annual colonoscopy.</li> <li>◆ FS with polypectomies every 4-12 months when multiple adenomas found and subtotal colectomy and proctectomy done.</li> </ul>	<u>Familial Adenomatous Polyposis</u> <ul style="list-style-type: none"> <li>◆ Upper endoscopy should be done when colorectal adenomas are identified, and repeated every two years.</li> <li>◆ When multiple adenomas are found, prophylactic colectomy should be performed (by age 30)</li> <li>◆ If proctocolectomy done, there is no need for further GI evaluation</li> </ul>
Colonoscopy	<u>Family history of sporadic colorectal cancer</u> <ul style="list-style-type: none"> <li>◆ Colonoscopy beginning at age ten years less than affected family member, or at age 40 (whichever comes first), then every 5 years until two consecutive normal studies, then as for average risk.</li> </ul> <u>Personal history of colorectal cancer</u> <ul style="list-style-type: none"> <li>◆ Full colonoscopy at 6 &amp; 12 months post-resection (with biopsies of anastomotic line), repeat annually for 4 more years, then every 3 years.</li> <li>◆ FOBT and rectal exam annually when interval between colonoscopies &gt; 1 year.</li> <li>◆ CEA every 6 months x 3 then annually for five years</li> </ul>	<u>Family history of sporadic colorectal cancer</u> <ul style="list-style-type: none"> <li>◆ Single first degree relative with colon cancer (2-4 fold increased risk)</li> <li>◆ More than one first degree relative (FDR), same surveillance as for one FDR.</li> <li>◆ If &gt; 2 FDRs, look for other evidence of HNPCC</li> </ul>

## Colon Cancer Screening Recommendations

Screening Procedure	Frequency by disease category
Colonoscopy	<p data-bbox="351 985 384 1576"><u>History of Removal of an Adenomatous polyp</u></p> <ul data-bbox="409 197 640 1559" style="list-style-type: none"> <li data-bbox="409 197 484 1559">♦ Single or a small number of adenomatous polyps: colonoscopy every 3 years until no more polyps, then colonoscopy every 5 years.</li> <li data-bbox="500 251 574 1559">♦ Some patients with multiple adenomas or with suboptimal clearance of all polyps, may need repeat colonoscopy within 1 year, then re-evaluate.</li> <li data-bbox="599 570 640 1559">♦ Single small tubular adenoma, can follow-up with colonoscopy in 5 years.</li> </ul> <p data-bbox="682 895 715 1576"><u>Ulcerative Colitis (UC)</u> (1% of all colorectal cancers)</p> <ul data-bbox="740 134 863 1559" style="list-style-type: none"> <li data-bbox="740 985 773 1559">♦ Ulcerative proctitis - same as average risk.</li> <li data-bbox="789 134 863 1559">♦ Left-sided colitis - colonoscopies every 1-2 years beginning 12-15 years after diagnosis, with biopsies every 10 cm. Best done when colitis is inactive (dysplasia can be confused with acute inflammatory changes).</li> </ul> <p data-bbox="888 261 963 1495"><b>Low grade dysplasia</b> - treat UC aggressively and repeat colonoscopy in 3-6 months, or consider prophylactic proctocolectomy.</p> <p data-bbox="979 283 1053 1495"><b>High grade dysplasia</b> (or if low-grade dysplasia persists on repeat biopsies) strongly consider proctocolectomy.</p> <p data-bbox="1087 1272 1120 1576"><u>Universal or pan colitis</u></p> <ul data-bbox="1136 602 1169 1559" style="list-style-type: none"> <li data-bbox="1136 602 1169 1559">♦ Same as left-sides UC, but begin colonoscopies after 8 years of disease.</li> </ul> <p data-bbox="1210 1017 1243 1576"><u>Crohn's disease</u> (risk increased 7 to 20 fold)</p> <ul data-bbox="1268 208 1384 1559" style="list-style-type: none"> <li data-bbox="1268 208 1384 1559">♦ Begin screening after 10 years of disease: Colonoscopy every 2 years, biopsies of any stricture, polyp, nodule, fistula, or any suspicious lesions. Small bowel must be surveyed for cancer in long-standing ileal Crohn's.</li> </ul>

## PROCEDURES

## Pedigree Review

### Purpose:

The Pedigree review committee is a multidisciplinary team that reviews pedigrees from the FRAP program and the Network Risk Registry Program on a weekly basis to give feedback genetic diagnosis and identification of family members for further data collection and genetic studies.

### Tasks:

1. After Education session mail Surveys to Fox Chase. You can staple all surveys together since the Health History Questionnaire is the only form that has a name on it. There should be 4 surveys
2. Survey data is entered into High Risk Registry and Pedigree is generated.
3. On the following Tuesday, pedigrees are reviewed. The Pedigree review committee will provide preliminary feedback for the Pedigree Expansion
  - preliminary genetic diagnosis for maternal and paternal side of family
  - further information that needs to be collected by individual ID #
  - individuals identified for blood studies
  - individuals identified for collection of tissue samples
4. Mailed back will contain (estimated three week turn around)
  - pedigree review form (*attachment 1*)
  - enlarged pedigree for the patient
  - enlarged pedigree for pedigree expansion (*attachment 2*)
  - enlarged pedigree for mailing with the blood kit

# Pedigree Review

Network Hospital \_\_\_\_\_ Coordinator \_\_\_\_\_

Date of pedigree review \_\_\_\_\_ Date of pedigree expansion \_\_\_\_\_

Name: \_\_\_\_\_ Fam id# \_\_\_\_\_ Proband id# \_\_\_\_\_

## Diagnosis

## Reasons:

Maternal: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Paternal: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## Follow-up/Questions:

1. Family members for: Blood Tumor Medical Other  
Records

_____	[ ]	[ ]	[ ]	_____
_____	[ ]	[ ]	[ ]	_____
_____	[ ]	[ ]	[ ]	_____
_____	[ ]	[ ]	[ ]	_____
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_____	[ ]	[ ]	[ ]	_____
_____	[ ]	[ ]	[ ]	_____

Other Information: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_



Community Medical

Coord \_\_\_\_\_  
**Pedigree Review Recommendations**

Things to risk about

Date of pedigree review 5/21/96 Date of pedigree expansion pending

Name: \_\_\_\_\_ Fam id# \_\_\_\_\_ Proband id# 18260

Medical History: BR @ 36 ; then BR @ 45

check if she still has ovaries

**Prelim. Diagnosis**

**Reasons:**

Maternal: Familial Breast

mother only 2 breast at later age but 2 prostates  
Get more info on gr. parents may change picture  
Lines drawn from aunts/uncles & sibs - ck if they had children & any cancers?

Paternal: Spontaneous Breast  
only 1 breast, no clear  
pattern but limited # of females

get more family hx info on grandmothers  
side of family

**Recommendations:**

1. Eligibility

- ☒ research only  
☒ genetic testing research  
☐ other

**Reasons:**

if one gives

2. Family members for: Blood Tumor Medical Other

	Blood	Tumor	Medical Records	Other
• 18262	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<u>did she ever have a TAH.</u>
• 18260	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
• 18272	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
• 18273	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
• 18275	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
18279	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<u>get her father's family if she</u> <u>comes for Risk session</u>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Medical Surveillance:**

Should have baseline sigmoidoscopy

**Missing Information:**

## Pedigree Expansion/Individual Risk Assessment

### Purpose:

The Pedigree expansion is part of the individual risk assessment that is conducted by the Network Nurse/coordinator to:

- collect additional family, and medical information that may confirm or elucidate the cancer family pattern or genetic diagnosis
- provide information about the cancer family pattern and cancer risk
- give the opportunity to obtain confirmation of cancers through collection of medical records or pathology report
- give the option for participation in genetic studies for the proband and other family members.

### Tasks:

1. Set up appointment for Pedigree Expansion/Individual Risk Assessment
  - allow at least one hour for individual session
  - allow more time if family members come together
  - allow additional half hour if you will collect blood sample
2. Use Family Risk Counseling - Nursing Checklist as framework to collect individual and family medical history. (*Attachment 1*)
3. If information collected during the pedigree expansion has not changed, present:
  - preliminary genetic diagnosis
  - cancer pattern (sporadic, familial, hereditary)
  - cancer syndrome ( cancers associated with the syndrome)
  - ask if numbers help, if yes may use some of the statistics associated with having a family history or the cancer pattern.
4. Offer option for genetic testing research. If proband is interested obtain informed consent (*See Informed Consent section -ELSI consent 2* )
5. Mail expanded pedigree information back to Fox Chase in order to confirm or change preliminary genetic diagnosis.

( *See information from genetic counseling protocol.* Diagnosis is still preliminary because confirmation of all cancers has not been obtained. Only when you received medical records information confirming cancers does the information become more definite. Remind proband that information from the pedigree is not an exact science. There are limitations to the family history, that is why the hereditary pattern is called putative , i.e. assumed, because exact mutations through genetic studies have not yet been done.)

# FAMILIAL CANCER RISK COUNSELING - NURSING CHECKLIST

<b>Introduction</b> <input type="checkbox"/> Self and role <input type="checkbox"/> Purpose of family risk assessment <input type="checkbox"/> Assess expectations	<b>Family members without cancer</b> <input type="checkbox"/> Current age <input type="checkbox"/> Surgeries (TAH,BSO) <input type="checkbox"/> Health status <input type="checkbox"/> If deceased, age and cause of death  <b>Individuals with cancer</b> <input type="checkbox"/> cancer site/primary and metastasis <input type="checkbox"/> unilateral vs. bilateral <input type="checkbox"/> number of primaries <input type="checkbox"/> pathological diagnosis <input type="checkbox"/> age at diagnosis <input type="checkbox"/> place of diagnosis <input type="checkbox"/> name when diagnosed <input type="checkbox"/> current age or age at death <input type="checkbox"/> environmental exposure <input type="checkbox"/> other health problems (TAH,BSO)  <i>If client/proband</i> <input type="checkbox"/> treatments <input type="checkbox"/> follow-up recommendations <input type="checkbox"/> physician(s) involved in care	<b>Confirming Diagnosis</b> <input type="checkbox"/> Permission from affected relative, next of kin, or POA <input type="checkbox"/> Obtain pathology reports, hospital records, autopsy reports, physician notes, death certificate
<b>Client/Proband</b> <input type="checkbox"/> Current age <input type="checkbox"/> Occupation <input type="checkbox"/> Ethnicity/ Race : Maternal Paternal <input type="checkbox"/> Birth defects <input type="checkbox"/> Exposures: ethanol/drugs chemicals radiation talc environmental occupational <input type="checkbox"/> Physical findings a/w inherited forms of cancer benign skin moles familial polyposis <input type="checkbox"/> Cancer screening or dx procedures mammograms biopsies sigmoid or colonoscopy <input type="checkbox"/> Reproductive history age at menarche number of pregnancies live births age at first live birth stillbirths spontaneous/voluntary abortions menstrual periods OC or HRT use <input type="checkbox"/> Past history allergies meds surgeries illness <input type="checkbox"/> Current health status	<b>Risk Information</b> <input type="checkbox"/> Family pattern: maternal/paternal <input type="checkbox"/> Explanation of inheritance pattern e.g. what criteria makes it familial <input type="checkbox"/> Explanation of cancer syndrome what cancers involved <input type="checkbox"/> Describe limitations and certainty of dx <input type="checkbox"/> Explain A.D. inheritance pattern e.g. BRCA1 gene-dominant <input type="checkbox"/> Describe issues of penetrance <input type="checkbox"/> Risk estimate - ask if numbers help <input type="checkbox"/> Describe other factors that can contribute to risk <input type="checkbox"/> Explain risk for children	<input type="checkbox"/> Assess understanding and perception of risk <input type="checkbox"/> Recommendations screening & its limitations follow-up mechanism referrals genetic studies other relatives for assessment or genetic studies <input type="checkbox"/> Questions and plan
<b>Suggested Flow</b> <input type="checkbox"/> Spouse & children <input type="checkbox"/> Siblings <input type="checkbox"/> Parents <input type="checkbox"/> Aunts & Uncles <input type="checkbox"/> Grandparents		

## **Contacting Family Members for blood and/or tumor samples Relative Identification Form (RIF)**

### Purpose:

One of the major criteria for participation in genetic studies is to collect blood samples from one or more affected relatives with cancer. The affected relatives is the reference case necessary to determine genetic mutations associated with cancer. Contacting relatives is therefore necessary to proceed with the genetic testing research.

In order to confirm cancers, medical records or pathology reports need to be obtained. If the proband is not the next of kin, their relative or their next of kin need to be contacted to obtain permission for release of these records. If there are no living affected relatives, their next of kin can be contacted as well.

### Tasks:

1. Explain rationale for contacting relatives and indicate the relatives identified from the pedigree review form.
2. Ask if they would give permission to contact those relatives. Explain that:
  - We will not contact relatives without their permission
  - A letter will be mailed prior to contacting relatives to give them option to decline participation.
  - Only after the above 2 steps will relative be called and invited to participate in genetic studies and/or asked permission to obtain medical records for next of kin.
  - Relatives who live outside of area can participate in genetic studies via a mailed blood collection kit.
3. If they are willing get them to sign the Relative Identification Form (**attachment 1**) and complete the back side of form with relatives names, addresses and phone numbers.
4. If they are willing but want to check with relative first or get correct address, give them the RIF and have them mail it back. Pre-addressed and stamped envelopes facilitate the return of these forms.

5. Explain that a letter will be mailed to the relative(s) describing the program and giving them the opportunity to decline being contacted (**attachment 2**).

6. Once RIF is completed, mail letters to relative(s) and make a copy of the letter(s). Document the date mailed on back of RIF. Fill out a contact log form (**attachment 3**) with the date the letter was sent and a copy of the letter. Relative(s) can be contacted approximately two weeks after mailing date if they have not called back to decline.

7. Approximately 2 weeks after letter has been mailed, telephone the relative. Use High Risk Registry Telephone Script (**attachment 4**) to review purpose of participation in study. Have contact log with you when calling.

If they are willing to authorize release of information and/or tissue material for research, follow procedures for contacting relatives for medical records or tumor blocks

Proband ID number \_\_\_\_\_

Family ID number \_\_\_\_\_

Date RIF signed \_\_\_\_/\_\_\_\_/\_\_\_\_

THE FOX CHASE NETWORK  
Family Risk Assessment Program

**Relative Identification Form**

---

With the help of various doctors at Fox Chase Cancer Center, we have identified members of your family who are eligible to participate in the gene study determining risk for breast, ovarian, and/or colon cancer.

With your permission, we would like to contact your relatives telling them about this gene study. We will be asking them to donate a sample of their blood and to fill out an information sheet on their family history. There will be no costs involved.

---

**YES**     you have my permission to contact  
my blood relatives for this gene study

*Please sign below and complete the Relative Information Form*

\_\_\_\_\_

**NO**     I do not wish to have any of my relatives contacted for this gene study

*Please sign below and complete the Relative Information Form*

\_\_\_\_\_

**THANK-YOU**

Name of proband \_\_\_\_\_  
Family ID number \_\_\_\_\_

Relative's Name \_\_\_\_\_  
Address \_\_\_\_\_  
\_\_\_\_\_  
Phone \_\_\_\_\_  
Date of Birth \_\_\_\_\_  
Relationship \_\_\_\_\_  
ID# \_\_\_\_\_ diagnosis \_\_\_\_\_  
(Letter sent out \_\_\_\_\_)

Contact date \_\_\_\_\_  
Primary Care Provider \_\_\_\_\_  
Address \_\_\_\_\_  
\_\_\_\_\_  
Fax # \_\_\_\_\_  
Phone # \_\_\_\_\_

Relative's Name \_\_\_\_\_  
Address \_\_\_\_\_  
\_\_\_\_\_  
Phone \_\_\_\_\_  
Date of Birth \_\_\_\_\_  
Relationship \_\_\_\_\_  
ID# \_\_\_\_\_ diagnosis \_\_\_\_\_  
(Letter sent out \_\_\_\_\_)

Contact date \_\_\_\_\_  
Primary Care Provider \_\_\_\_\_  
Address \_\_\_\_\_  
\_\_\_\_\_  
Fax # \_\_\_\_\_  
Phone # \_\_\_\_\_

Relative's Name \_\_\_\_\_  
Address \_\_\_\_\_  
\_\_\_\_\_  
Phone \_\_\_\_\_  
Date of Birth \_\_\_\_\_  
Relationship \_\_\_\_\_  
ID# \_\_\_\_\_ diagnosis \_\_\_\_\_  
(Letter sent out \_\_\_\_\_)

Contact date \_\_\_\_\_  
Primary Care Provider \_\_\_\_\_  
Address \_\_\_\_\_  
\_\_\_\_\_  
Fax # \_\_\_\_\_  
Phone # \_\_\_\_\_

Relative's Name \_\_\_\_\_  
Address \_\_\_\_\_  
\_\_\_\_\_  
Phone \_\_\_\_\_  
Date of Birth \_\_\_\_\_  
Relationship \_\_\_\_\_  
ID# \_\_\_\_\_ diagnosis \_\_\_\_\_  
(Letter sent out \_\_\_\_\_)

Contact date \_\_\_\_\_  
Primary Care Provider \_\_\_\_\_  
Address \_\_\_\_\_  
\_\_\_\_\_  
Fax # \_\_\_\_\_  
Phone # \_\_\_\_\_

Relative contact letter  
Sample

<Network Hospital>  
<Address 1>  
<address 2>

<date>

<Name>  
<address 1>  
<address 2>

Dear <name>,

I am working with a Family Risk Assessment Program in cooperation with the Fox Chase Cancer Network on a genetic research study for relatives who have a family member with breast cancer.

Your <relative, name> who has participated in the program, has given us permission to contact you. In the near future, we will call you to tell you more about this research study. You would be asked to

< donate a sample of your blood and provide us with information on your family history>

or

< give us permission to obtain medical records on your relative with breast cancer>

There are no costs involved. Your participation would help us to advance the science related to breast cancer and may help to determine the risk for breast cancer in your female blood relatives.

If you do not wish to be contacted please call me at (Phone number> and request that you not be called. Thank You.

*within 2 weeks*

Sincerely,

<Network Staff Name>  
<Network staff title>



High Risk Registry  
Script to Request Blood Sample from Relatives

Hello. My name is ... I am a <title> at the <name of hospital>. With your (sister, mother, aunt, etc. give name of relative-) \_\_\_\_\_ permission, we recently mailed you a letter describing a study we are conducting with someone like yourself who has a relative with breast cancer. I am calling to ask if you received the letter, to explain this program, to answer any questions you may have, and to see if you would be willing to participate.

Would this be a good time for you to talk?

Yes \_\_\_\_\_ No \_\_\_\_\_

Arrange for call back \_\_\_\_\_

**A. Description of Program**

I am working in a program in Hereditary Breast Cancer. This program is for persons who have relatives with breast cancer and some other related cancers. As you may already know, breast cancer tends to run in certain families. Cancer of the ovary appears to be more frequent in these families as well. Scientists believe that people in these families who have these cancers may have inherited a particular cancer gene. This gene is passed down from generation to generation in these families. Some family members will inherit the gene and others will not.

We are working with Fox Chase Cancer Center. We are studying the genes of families that have high rates of breast cancer to try to identify the gene alterations for cancer. In the near future, gene testing will help family members know if they have inherited a cancer gene. Then they would be better able to make decisions about screening practices or preventive surgery. So we are asking persons with a family history of cancer like yours to donate a sample of your blood for the purpose of studying the genes that have been related to breast cancer or help us in the research by giving us permission to obtain your relative's medical records of tumor tissue sample.

Because this is a study, the tests we are doing are experimental. It sometimes takes several months to a year, even longer before the research is complete. If results are available, you would be given the option to receive the results.

Would you be interested \_\_\_\_\_ yes      no \_\_\_\_\_

If no reason for decline \_\_\_\_\_

If yes, explain instructions for blood kit or to release medical records/tumor tissue.

## **Contacting Relative for Medical Records or Tumor Blocks**

Use telephone script to review purpose of study. If they are willing to participate explain the following procedures:

1. Explain that you will be sending them a letter with an authorization for release of information/and or tumor tissue.
  - if relative is the patient letter and release form can go directly to them.
  - if relative is the next of kin, explain that they can legally sign the release form
2. Instruct the relative that the release form will be mailed back to you at the hospital because it is easier for medical institutions to obtain records/tumor blocks.
3. Mail out letter describing program and the instructions for filling out the medical release form (**attachment 1 and 2**) along with your institution's release of medical information form (**attachment 3**)
4. Once you receive the completed release form mail it to the designated facility with a cover letter (samples -attachment 4).
5. Once medical records are returned. Confirm the reported cancer with the pedigree. Call Honey Salador (215) 728-2791 to report confirmation or correction of reported cancer.
6. Tumor blocks need to be sent to:
  - Josephine Costalas, MS
  - Cancer Genetics Counselor
  - Fox Chase Cancer Center
  - 510 Township Line Road
  - Cheltenham, PA, 19012

<date>

<relative's name>

<address>

<address>

Dear Ms. <relative's name>,

We would like to obtain some <medical records or tumor tissue material> from your surgery and confirm the type of tumor it was. This research will help to advance the science of how genes are related to different types of cancer in families.

Enclosed with this letter, please find one or more copies of an authorization form to release <medical records or tissue samples> to us. Please sign the form(s) and mail the form(s) back to me in the enclosed envelope; I will take care of mailing them out to the hospital(s).

If you have any questions, please do not hesitate to give me a call. My number is <phone number>. Thank-you for your help.

Sincerely yours,

<network staff>

<title>

## FOX CHASE CANCER CENTER

To whom it may concern,

The Family Risk Assessment Program<sup>®</sup> at the <Network Hospital> is presently assessing risk for cancer in individuals who have a family history of cancer. You have been given a form to fill out and sign to help us obtain information from your medical record (or from the medical record of one of your relatives) to verify the type of tumor you or your relative was reported to have had. This form may also help release to us some sample of tissue which was removed during your surgery or from the surgery of one of your relatives. Strict medical confidentiality will be maintained.

When this form has been filled out and signed, please mail it to the address above or in the self addressed envelope provided to you. There are no costs involved and your participation would help us to advance the science related to cancer.

Here are instructions on filling out this form:

Item #:	Instructions:
1	Your name
2	Name of hospital that patient (you or your relative) had surgery at
3,4	Patient's last and first name at time of surgery
5	Patient's maiden name (for married women)
6	Social Security Number (if known, otherwise not necessary)
7	Patient's date of birth
8	Patient's address at the time of surgery
9	If patient is deceased, please write in the day patient passed away
10	The month and/or year the surgery was done
11	Your signature (when possible, please include documentation confirming you have authority to sign for your relative)
12	State your relationship to the patient (self, daughter, son, etc.)
13	Date this form was signed by you
14	Signature of a witness
15	Date this form was signed by the witness

If you have any questions concerning filling out this form, please <Network nurse>, at <phone number>. Thank-you very much.

# <network hospital name>

## Authorization For Release of Medical Records and/or Tissue Material

I, the undersigned, \_\_\_\_\_  
Name of patient or person in lieu of patient requesting release of information; please print

Authorize the establishment \_\_\_\_\_  
Name of hospital or establishment patient treated at

To forward to      <network FRAP director>  
                         <network hospital name>  
                         Family Risk Assessment Program  
                         <address>  
                         <address>  
                         <phone number>

The following:

\_\_\_\_\_ Pathology tumor tissue (paraffin embedded blocks or slices)  
\_\_\_\_\_ Pathology report  
\_\_\_\_\_ other \_\_\_\_\_

Appearing in the medical record of

\_\_\_\_\_  
Last name

\_\_\_\_\_  
First name

\_\_\_\_\_  
Maiden Name

\_\_\_\_\_  
Social Security Number

\_\_\_\_\_  
Date of birth

\_\_\_\_\_  
Date of death

Concerning the following time period \_\_\_\_\_

\_\_\_\_\_  
Signature of patient or person authorized to sign in lieu of patient      indicate relationship to patient      Date of signature

\_\_\_\_\_  
Witness to signature      Date of signature

**Please note:** This form must be signed by the patient or by the person authorized to sign in lieu of patient (the executor or administrator of the decedent's estate, or by the next of kin).

FRAP number \_\_\_\_\_ id # \_\_\_\_\_ FRAP only \_\_\_\_\_ other \_\_\_\_\_

June 13, 1996

<hospital>  
MEDICAL RECORDS DEPARTMENT  
<address>  
<address>  
<phone number>

To whom it may concern,

The Family Risk Assessment Program at <Network hospital name> is presently assessing risk for cancer in patients who have a family history of cancer. In order to achieve close estimates of risk, we would like to acquire the information marked on the enclosed form to verify the type of cancer the indicated individual was reported to have had. Strict medical confidentiality will be maintained; there will be no publication of this patient's or family's name in any research literature. This form has been signed by the patient or by the person authorized to sign, in lieu of the patient.

Please forward this information to:

<Network hospital FRAP director>  
<address>  
<address>

These records will be used for research purposes only. We would, therefore, request that any charge for this service be waived by your institution, if at all possible. If there are questions, please feel free to call me at <phone number>. Thank-you very much for your help.

Sincerely yours,

<Network staff name>  
<title of staff>

June 13, 1996

<hospital>  
PATHOLOGY DEPARTMENT  
<address>  
<address>  
<phone number>

To whom it may concern,

The Family Risk Assessment Program<sup>®</sup> at the <Network hospital name> is presently assessing risk for cancer in individuals who have a family history of cancer. Enclosed, please find information you may need for release of pathology reports and/or paraffin embedded tumor (with or without normal) tissue blocks you may have available from the person we have indicated in the enclosed form. The reports and tumor blocks will be used for research purposes only. We would, therefore, request that any charge for your services be waived by your institution, if at all possible. Strict medical confidentiality will be maintained; there will be no publication of this patient's or family's name in any research literature.

Please forward this information to:

<Network hospital FRAP director>  
<address>  
<address>

The blocks will be returned to you after we have obtained the appropriate amount for our studies. If you have any questions, please feel free to call me at (215) 728-2727 or at (800) 325-4145. Thank-you very much for your help in obtaining this information.

Sincerely yours,

<Network staff name>  
<title of staff>

*may be cleaner to have  
it sent from protocol nurse  
d/t competition*

## **Contacting Relatives for Blood Studies**

If they are willing to authorize to give blood for research purposes:

- make appointment for them to come in for blood draw, if they live in area. See procedures for blood collection from a proband (or from a proband's relative) at your hospital.
- review procedures for Blood Collection for proband's relative outside of Network Hospital, if they do not live in your area.



## Blood Collection

### Purpose:

The purpose of blood collection is to obtain blood for genetic studies and for storage as part of the FCCC Network Breast Cancer Risk Registry.

Below are procedures for collecting blood from a proband at your hospital, from a relative at your hospital and from a relative out of the area.

### **A. Blood Collection from a Proband at your Hospital:**

#### Tasks:

1. Collect 2-4 tubes per individual depending on cancer status.
  - person with a personal history of cancer: obtain 4 tubes
  - high risk individual: obtain 2 tubes
2. Hand write labels, using labels affixed to tubes for each tube used.  
Include on label:
  - participant's first name
  - family ID#
  - participant ID#.
3. Draw blood into 2 or 4 yellow top tubes (unless otherwise specified). We ask that you invert the tubes gently seven times to allow the anti-coagulant to mix thoroughly with the blood.
4. Complete the Lab Information Form (**attachment 1**)
5. Place tubes inside Styrofoam shell. Use rubber band to secure lid.  
Inside the Ziploc bag place:
  - the Styrofoam shell
  - the completed Lab Information Form (**attachment 1**)
  - pedigree with proband highlighted (**attachment 2**)
  - \* **Only send pedigree once with proband's blood**

Place the bagged Styrofoam bag in the box, seal the ziploc bag, and close the box. Keep the box with blood samples at room temperature only. Do not refrigerate.

6. Affix Federal Express U.S. Airbill provided to box.(**attachment 3**).

7. Contact Federal Express at 1-800-238-5355 for access and pick-up times. Please mail blood the **same day** blood was drawn.
8. When sending blood to FCCC, use a separate box for each individual from whom you collect blood.
9. **IMPORTANT:** Blood samples can be collected Monday through Thursday only. Please do not mail bloods on a Friday or Saturday. They would arrive at Fox Chase over the weekend when no one would be here to receive or process the blood.
10. Once blood has been collected complete a "On Study Form." Fill in form according to protocol like other studies except:
  - ID # - use Social Security # unless you have a Medical Record #
  - Sequence # - Use the patient ID number from the pedigree
  - Date on study is the date blood is collected
  - Name of protocol - use "DOD".

Fax the form to the Fox Chase Cancer Center Protocol Office to the attention of Dorothy Kelly or Colleen Bonjo.

**For every person who participates in the Genetic Testing Research, i.e. blood or tissue samples received at FCCC, you will receive .5 credit.**

**B. Blood Collection from a Proband's Relative at a Network Hospital:**

Tasks:

1. Follow the same steps as outlined above for a proband's relative, except you do not have to mail a second family pedigree.

### C. Blood Collection from a Proband's Relative outside Network Hospital:

Follow RIF procedures for contacting relatives. After contact, if relative agrees to give blood for research, follow the tasks below.

#### Tasks:

1. While on the phone, obtain name of primary care provider and write it on backside of contact log form (see RIF procedures). Explain that a letter will be mailed or faxed to their provider to explain the research and request blood be drawn gratuitously.
2. Review with the relative the materials in the blood collection kit they will be receiving in the mail and the procedure for obtaining blood (use **attachment 4** to explain). Please stress the importance of their reading, signing, and returning the informed consent sheet to you.
3. After the phone call, call doctor's office to verify address and obtain fax # (if available). If fax # is available, send letter (**attachment 5**) with fax cover sheet (**attachment 6**). If fax # is not available, just mail the letter. The letter is sent to the relative's doctor about your study and request he/she to obtain a sample of blood at no charge to their patient.
4. Upon agreement from relative's doctor (letter with doctor's signature is sent back via mail or fax) to obtain blood, send blood kit to relative. Follow steps **1, 2, 5, 6, 8, 9** of section A: Blood Collection from a Proband at your Hospital. These steps are also mentioned in attachment 4.

Before mailing out the kit, this mailing must include:

- a letter that explains the contents of the blood kit (**attachment 7**)
  - Lab Information Form which will serve as lab request and instruction sheet (**attachment 1**). Complete items up to date of blood draw and the number of tubes requested under Lab Instructions section before sending to relative.
  - instructions for packaging and mailing blood samples (**attachment 4**).
5. Remember, if collecting blood for multiple members of a household, send separate kits to each person.
  6. Attachment 4 instructs the relative to read, sign and mail back the informed consent to you. When you receive a copy of the informed consent, that will serve as documentation for the date of the blood draw. You can then fax your "On Study Form" to the protocol office.

## Lab Information Form

Family ID# \_\_\_\_\_

Participant ID # \_\_\_\_\_

Number of tubes requested \_\_\_\_\_ 2 \_\_\_\_\_ 4 \_\_\_\_\_ other

Where blood was drawn (Please check one)

\_\_\_\_\_ FCCC

\_\_\_\_\_ Network hospital \_\_\_\_\_ (Institution)

Contact Name \_\_\_\_\_ Phone \_\_\_\_\_

\_\_\_\_\_ Other outside facility

Date blood drawn: \_\_\_\_\_

Number tubes obtained \_\_\_\_\_

Time of blood draw \_\_\_\_\_

---

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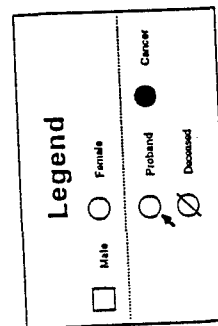
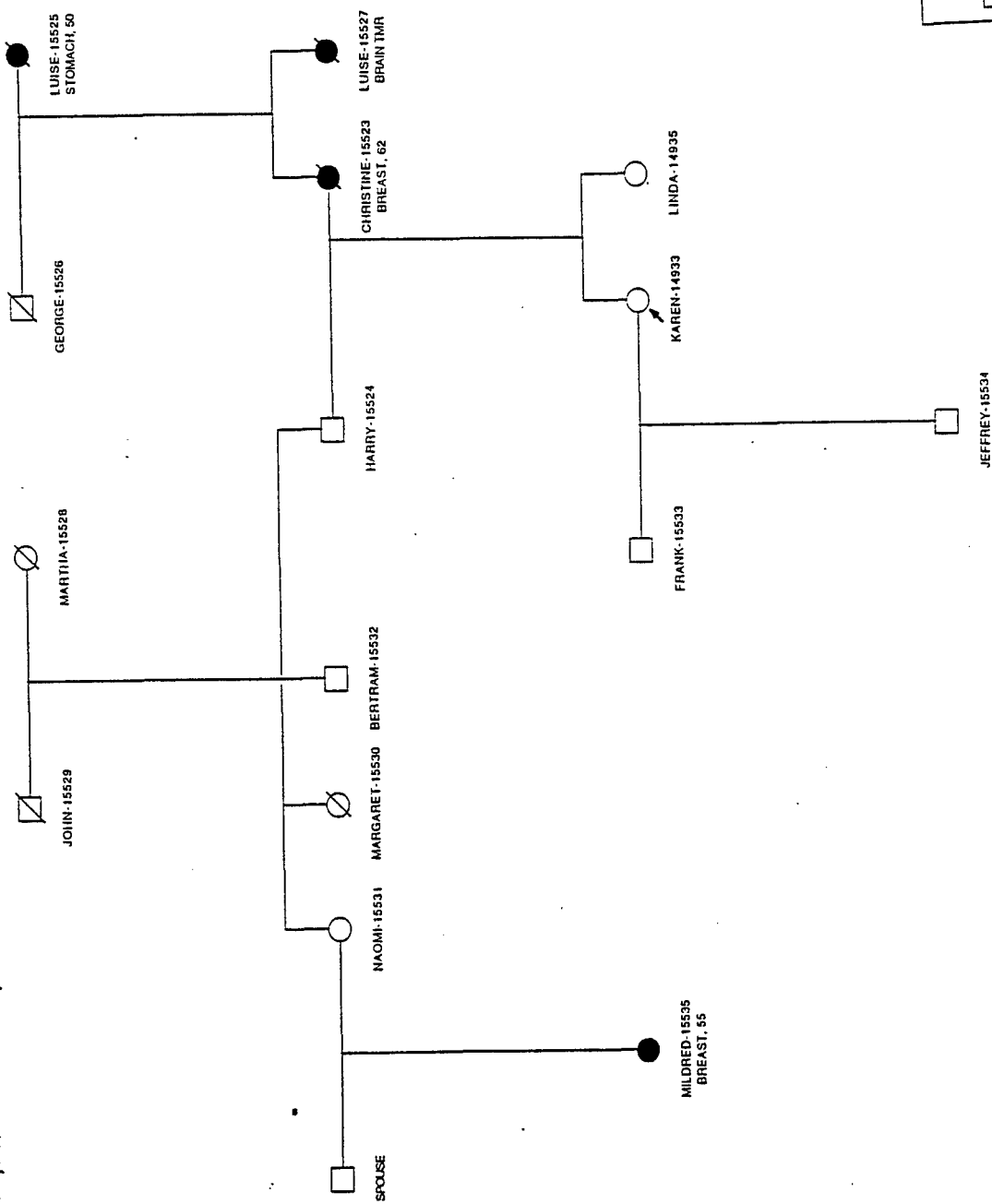
### Lab Instructions

- Please draw \_\_\_\_\_ full tubes of blood.
- Fill in above information: date and time of blood draw, and number of tubes obtained.
- Invert yellow top tubes gently seven times to allow the anti-coagulant to mix thoroughly with the blood.
- Return the yellow top tubes and this form in the Styrofoam box to the patient who will package and Federal Express these samples to the Fox Chase Cancer Center.

THANK YOU

---

FAM= 702,PROB= 14933,MR=



# FedEx

## USA Airbill

Tracking Number **8079739673**

1 From (please print)

Date **1031-5580-0**

Sender's Name **Dr. Andy Godwin** Phone \_\_\_\_\_

Company **FOX CHASE CANCER CENTER**

Address **7701 BURHOLME AVE**

City **PHILADELPHIA** State **PA** Zip **19111**

2 Your Internal Billing Reference Information (Optional) (First 24 characters will appear on invoice) **CC51081 grant7703**

3 To (please print)

Recipient's Name **Dr. Andy Godwin** Phone \_\_\_\_\_

Company **Fox Chase Cancer Center** Dept./Floor **W363**

Address (to ZIP at FedEx location, print FedEx address here) **7701 Burholme Ave.** (We cannot deliver to PO Boxes or P.O. Codes)

City **Philadelphia** State **PA** Zip **19111**

For "HOLD" Service check here

☐ Weekday ☐ Saturday ☐ Sunday (Not available with FedEx First Overnight)

For Saturday Delivery check here

☐ (Extra Charge. Not available to all locations) ☐ (Not available with FedEx First Overnight or FedEx Standard Overnight)

Service Conditions, Declared Value, and Limit of Liability - By using this Airbill, you agree to the service conditions in our current Service Guide or U.S. Government Service Guide. Both are available on request. See back of Sender's Copy of this unit for information and additional terms. We will not be responsible for any claim in excess of \$100 per package whether the result of loss, damage, or delay, non-delivery, misdelivery, or misrouting, unless you declare a higher value, pay an additional charge, and document your actual loss in a timely manner. Your right to recover from us for any loss includes the value of the package, loss of sales, interest, profit, attorney's fees, costs, and other items of damage, whether direct, incidental, consequential, or special, and is limited to the greater of \$100 or the declared value per package. The maximum declared value for any FedEx First Overnight or FedEx Standard Overnight package is \$500. Federal Express Inc., upon your request, and with some limitations, extend an exception charge for paid. See the FedEx Service Guide for further details.

Questions?  
Call 1-800-Go-FedEx

Sender's Copy  
**65 1000 10949428 5306N**

#### 4 Service\*

☒ FedEx Priority Overnight (Next business morning) ☐ FedEx Standard Overnight (Second business day) ☐ FedEx Govt. Overnight (Authorized user only) ☐ FedEx 2Day Freight (For packages over 150 pounds. Call for delivery schedule.) ☐ FedEx Overnight Freight ☐ FedEx 2Day Freight

☐ NIM/FedEx First Overnight (Excludes next business morning delivery to select locations) (Higher rates apply)

\*Delivery commitment may be later in some areas

#### 5 Packaging

☐ FedEx Letter\* ☐ FedEx Pak\* ☐ FedEx Box ☐ FedEx Tube ☒ Other Packaging (Declared value limit \$200)

#### 6 Special Handling

Does this shipment contain dangerous goods? **No** ☐ Yes (As per attached Shipper's Declaration) ☐ Yes (Shipper's Declaration not required) ☐ Dry Ice (Dangerous Goods Shipper's Declaration not required) ☐ CA ☐ Cargo Aircraft Only

#### 7 Payment

Bill To: ☒ Sender (Account due in section 1 with fee label) ☐ Recipient ☐ Third Party ☐ Credit Card ☐ Cash/Check (Enter FedEx account no. or Credit Card no. below)

FedEx Account No. \_\_\_\_\_ Exp. Date \_\_\_\_\_  
Card No. \_\_\_\_\_ Exp. Date \_\_\_\_\_

Total Packages \_\_\_\_\_ Total Weight \_\_\_\_\_ Total Declared Value\* \$ \_\_\_\_\_ Total Charges \$ \_\_\_\_\_

\*When declaring a value higher than \$100 per package, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE AND LIMIT OF LIABILITY section for further information.

#### 8 Release Signature

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

**232**

How Date 7/95 • 1001 • 14 280  
• 1994 25 • 1001 • 14 280  
• 1994 25 • 1001 • 14 280

The World On Time

## Instructions for Packaging and Mailing Blood Samples

### This Blood Collection Kit contains:

- \* form(s) to release tumor tissue or medical records (you may or may not receive this)
- \* 2 Medical Consent Forms - One is for you to keep and one to mail back.
- \* 1 box with a styrofoam shell containing blood collection tubes (for packaging and mailing)
- \* 1 plastic bag
- \* a Participant Information Form for the technician drawing your blood
- \* a set of instructions for packaging and mailing your blood samples to Fox Chase Cancer Center
- \* 1 envelope for mailing any forms to us

### Having your blood taken:

Fasting from food or drink is not required

Please read and sign both the Medical Consent Forms before having your blood taken. **Keep** one copy for your records and **send** the other back to us using the envelope. Use the enclosed envelope provided to mail this and any other forms we have sent you.

Call to make an appointment with your doctor when you are ready to have your blood taken.

Please have your blood sample taken on a Monday, Tuesday, Wednesday, or Thursday and take the entire kit with you to the doctor's office.

Give the Participant Information Form to the technician who will be taking your blood.

### After your blood sample has been taken . . .

Carefully place the full tubes inside the styrofoam shell. Use rubber band to close.

Place the styrofoam shell and the Participant Information Form inside the plastic Ziploc bag. Do not forget to write the date and time your blood was drawn on this form.

Place the bagged styrofoam shell inside the box; close the bag and the box. Keep the box with the blood samples at room temperature only.

### Mailing the Blood Collection Kit to Fox Chase Cancer Center:

Fox Chase Cancer Center will be billed directly, so do not pay any mailing costs. You must mail your blood samples **the same day** it was taken!

Call Federal Express at **1-800-238-5355** the day before or as soon as your blood has been taken, to arrange a time to pick up your package. However, you need to call Federal Express no later than **3pm** in order to have the blood picked up on the same day it was taken. In the meantime, keep the blood at room temperature only.

When FedEx has picked up your blood sample, call Honey Salador at (800)325-4145 or (215)728-2704. Leave your name and the date your blood was picked up. Thank-you very much for your participation.

<date>

<doctor's name>  
<address>  
<address>  
<phone number>

Dear Dr. <name>,

We are working with other doctors from the Fox Chase Cancer Center on a genetic study of relatives with a family history of cancer. This genetic research study is for the purpose of research only and all results are kept confidential. If successful, it may someday be possible to identify persons who are highly susceptible to certain forms of cancer.

**<name of relative>** is a relative of a patient seen at <network hospital name>. <she/he> is willing to donate a sample of blood for our genetic research study and has been provided with a blood collection kit. We would appreciate your assistance in this study by obtaining the blood sample for us without charge to this patient, if possible. <she/he> has been given a set of instructions to send the blood samples back to Fox Chase Cancer Center for analysis. The mailing expenses will be covered by Fox Chase Cancer Center.

Please sign a copy of this letter and fax or mail it back to us, if you are willing to assist us in obtaining blood samples for this study. If you have any questions, you may call either one of us <phone number>. Our fax number is <phone number>. We thank-you in advance for your help and cooperation and for waiving your usual fee for phlebotomy. Thank-you.

Sincerely yours,

\_\_\_\_\_  
<network FRAP director>  
Director

\_\_\_\_\_  
<network staff name>  
<title>

\_\_\_\_\_  
Doctor's signature

\_\_\_\_\_  
Date



<NETWORK  
hospital name>

<Network staff name>  
<address>  
<address>  
<phone number>  
<fax number>

## FAX Cover Sheet

To: <doctor's name?  
From: <network staff name>  
Date: <date>  
No. of Pages: <no. of pages> (including cover sheet)

Please deliver immediately!

Message: Thank-you very much for all your help.

Call <network staff name> <phone number> if there are any problems with this transmission.

Please note!

The information contained in this FAX is legally privileged and confidential information intended only for the use of the individual named above. If the receiver of this message is not the intended recipient, you are hereby notified that any unauthorized dissemination, disclosure, distribution, or copy of this FAX is strictly prohibited. If you have received this FAX in error, please immediately notify me by telephone to arrange for the proper return of this information. Thank-you.

<date>

<name>  
<address1>  
<address2>

Dear <name>,

Thank you for your willingness to participate in our **Genetic Research Studies in Hereditary Cancer** at <name of Network Hospital>. As we discussed, participation in this study requires that you donate a sample of your blood. Your blood will be used solely for the purpose of research. Results from this study will be kept confidential. This research will help to advance the science of how genes are related to certain kinds of cancer.

**This Blood Collection Kit** contains:

- \* form(s) to release tumor tissue or medical records (you may or may not receive this)
- \* 2 Medical Consent Forms - One is for you to keep and one to mail back.
- \* 1 box with a styrofoam shell containing blood collection tubes (for packaging and mailing)
- \* 1 plastic bag
- \* a Participant Information form for the technician drawing your blood
- \* a set of instructions for packaging and mailing your blood samples to Fox Chase Cancer Center
- \* 1 envelope for mailing forms to us

We would greatly appreciate it if your blood could be drawn **soon** (within 2 to 3 weeks) after receiving this kit. Your blood should be taken by a qualified lab technician at a doctor's office or hospital laboratory. If you have any questions or need further assistance, please call me, <name> at <phone>.

Sincerely yours,

<Network staff>

## **APPENDIX B**

## **Familial Cancer Risk Counseling**

### **Pretest**

*As part of the Familial Cancer Risk Counseling Training, you are asked to complete the following questions. The purpose of this test is to help us evaluate the course. No grade will be given. We also realize that most nurses will not have the answers for some of the questions. However, we ask that you answer to the best of your ability without use of reference materials.*

**Please complete this test and bring it with you on May 16, 1995.**

**NAME** \_\_\_\_\_ **DATE** \_\_\_\_\_

## TEST QUESTIONS

### Principles of Basic Genetics

1. Match each genetic disorder on the left with the correct inheritance pattern. (Autosomal Dominant = AD; Autosomal Recessive = AR; X-linked = X; Chromosomal = C; Multifactorial, polygenic, non-Mendelian = M).

[ANSWER: \_\_\_\_]

- |                                   |       |
|-----------------------------------|-------|
| a) Cystic Fibrosis                | _____ |
| b) Huntington's Disease           | _____ |
| c) Fragile X                      | _____ |
| d) Arthritis                      | _____ |
| e) Phenylketonuria                | _____ |
| f) Down's Syndrome                | _____ |
| g) Neurofibromatosis, type I      | _____ |
| h) Non-insulin dependent diabetes | _____ |
| i) Turner Syndrome                | _____ |
| j) Tay Sachs Disease              | _____ |
| k) Marfan Syndrome                | _____ |
| l) Cancer (tricky!)               | _____ |

2. Human chromosomes are composed of a complex of all except which one?

- a) DNA
- b) histones (basic protein)
- c) non-histone protein
- d) RNA

[ANSWER: \_\_\_\_]

### Molecular genetics of carcinogenesis

3. Which of the following is not a stage of carcinogenesis?

- a) initiation
- b) mutation
- c) promotion
- d) progression.

[ANSWER: \_\_\_\_]

4. Which best describes a type of genetic change associated with cancer?

- a) autosomal transmission
- b) phenotypic expression
- c) mismatch repair genes.

[ANSWER: \_\_\_\_]

5. A gene that induces uncontrolled cell growth and proliferation is which of the following?
- a) oncogene
  - b) tumor suppressor gene
  - c) candidate gene.

[ANSWER: \_\_\_\_]

#### Human Genome Project and Genetic Testing

6. The primary goals of the human genome project include:
- a) Constructing detailed genetic linkage maps
  - b) Isolating the genes contained within chromosomes
  - c) Constructing physical maps of chromosomes.
    - 1) a and b
    - 2) b and c
    - 3) a, b, and c.

[ANSWER: \_\_\_\_]

7. Which of the following is not a method of direct testing?
- a) DNA sequencing
  - b) Linkage analysis
  - c) PCR.

[ANSWER: \_\_\_\_]

8. Which of the following techniques can amplify a DNA sequence, hundreds of millions of times in a matter of hours?
- a) FISH
  - b) Cloning
  - c) PCR.

[ANSWER: \_\_\_\_]

#### Inherited Patterns of Cancer

9. What are some of the indications obtained from a family history that would necessitate further cancer genetics counseling and screening?
- a) Breast, ovarian and/or other clusters of cancer;
  - b) Bilateral breast cancer;
  - c) Early age of onset (before age 45);
  - d) Multiple primary tumors;
  - e) Vertical transmission of cancers and in multiple family members;
  - f) All of the above.

[ANSWER: \_\_\_\_]

10. Which organ is not considered as part of the spectrum of organs at risk for tumors in the Hereditary Non Polyposis Colorectal Cancer Family Syndrome (HNPCC)?

- a) colon;
- b) ovary;
- c) endometrium;
- d) stomach;
- e) brain.

[ANSWER: \_\_\_\_]

11. Which cancer genetic syndrome is not considered as part of the Polyposis and Non-Polyposis Colorectal Cancer Family Syndromes?

- a) Familial Adenomatous Polyposis (FAP);
- b) Flat Adenoma Syndrome (FAS);
- c) Lynch I (HNPCC I);
- d) Peutz-Jegher Syndrome;
- e) Li-Fraumeni Cancer Family Syndrome.

[ANSWER: \_\_\_\_]

Obtaining and interpreting family history information

12. Which of the following would not be included as a purpose for obtaining a cancer family history?

- a) To formulate cancer risk diagnosis
- b) To educate client
- c) To change a client's perception of risk
- d) To provide basis for cancer screening guidelines.

[ANSWER: \_\_\_\_]

13. Ideally, data on how many generations should be included in the family history?

- a) one
- b) two
- c) three.

[ANSWER: \_\_\_\_]

14. What steps would you take to confirm a cancer diagnosis in a maternal aunt of the proband?

- a) Verbally confirm diagnosis with the aunt
- b) confirm diagnosis from medical records
- c) b only
- d) a & b.

[ANSWER: \_\_\_\_]

15. What information would you obtain on family members who have had cancer?

- a) Cancer site
- b) Number of primary cancers
- c) Age at diagnosis
- d) Environmental exposures
- e) All of the above.

[ANSWER: \_\_\_\_]

Familial Cancer Risk Information

16. A risk estimate that provides an estimation of cancer risk for each subsequent decade of life based on specific variables is called:

- a) relative risk
- b) lifetime risk
- c) cumulative risk
- d) absolute risk.

[ANSWER: \_\_\_\_]

17. The Claus model allows for estimation of risk for individuals with a family history of which cancer:

- a) breast
- b) ovarian
- c) colon.

[ANSWER: \_\_\_\_]

18. BRCA1 carriers are estimated to have a lifetime risk for breast cancer that may be as high as:

- a) 50%
- b) 75%
- c) 90%.

[ANSWER: \_\_\_\_]

19. Which risk model would provide the most appropriate estimate of risk for a woman undergoing regular screening for breast cancer and having a sporadic family pattern of breast cancer:

- a) Claus model
- b) Gail model
- c) LOD score.

[ANSWER: \_\_\_\_]



### Nursing Role in Providing Familial Cancer Risk Information

20. Which are the best models for providing risk information for an individual with familial pattern (moderate risk) for breast cancer?

- a) relative risks
- b) cumulative
- c) family history.
  - 1) a only
  - 2) c only
  - 3) a and b
  - 4) b and c.

[ANSWER: \_\_\_\_]

21. Which of the following is critical to complete before providing an individual or family with risk information and medical follow-up recommendations?

- a) Obtain a cancer family history only
- b) Correct an individual's misperception of risk
- c) Obtain a cancer family history and have cancer diagnoses confirmed.

[ANSWER: \_\_\_\_]

22. Which of the following reasons might explain why someone with a strong family history of cancer may not have a hereditary cancer?

- a) Shared environment
- b) A common cancer in large family pedigrees may occur more often by chance
- c) a and b.

[ANSWER: \_\_\_\_]

### Medical Management and Surveillance

23. Prophylactic surgery provides 100% efficacy in preventing a cancer.

- a) True
- b) False

[ANSWER: \_\_\_\_]

24. Which of the following are potential risks associated with prophylactic surgery?

- a) Psychological risk
- b) Surgical complications
- c) Need for hormone replacement.
  - 1) a & b
  - 2) b & c
  - 3) all of the above.

[ANSWER: \_\_\_\_]

25. Which of the following experimental methods are most utilized in screening for ovarian cancer in high risk women?

- a) Pelvic exam, CEA & transvaginal ultrasound
- b) CT scanning and pelvic exam
- c) Pelvic exam, CA125, and transvaginal ultrasound.

[ANSWER: \_\_\_\_]

Psychosocial impact of cancer risk information

26. True or False:

Emotional reactions to cancer risk information include anxiety, fear, embarrassment and guilt.

- a) True
- b) False.

[ANSWER: \_\_\_\_]

27. You have recognized that the client is in need of a referral to a mental health professional. You tell the client which of the following?

- a) Many people get depressed and need medication after being told of genetic risk for cancer.
- b) You ask the client if they believe there is a problem which they would like to address.
- c) You are not the right person to help the client address his/her problem.
- d) You know the counselor to whom you will refer the client.
- e) You must refer to a counselor because of legal issues.

[ANSWER: \_\_\_\_]

28. A woman comes to your clinic and learns that she is at increased risk of breast cancer. Her mother died five years ago of the same disease. As the client tells you how guilty she feels at not spending more time with her mother during her last months, you respond by:

- a) Telling her that guilt is a wasted emotion and that she will need all of her emotional energy channeled toward fighting her own disease.
- b) Allowing her time to discuss what she did do to care for her mother, encouraging her to see that she did what her time/energy permitted her to do during a frightening, difficult time.
- c) Telling her to relate the story to her daughter so that her daughter does not have the same regrets later.

[ANSWER: \_\_\_\_]

### Visioning Genetics for the Future

29. Which of the following are considered ethical and/or legal concerns related to predictive testing for cancer susceptibility?

- a) Informed consent
- b) Privacy and confidentiality
- c) Discrimination issues
- d) All of the above.

[ANSWER: \_\_\_\_]

30. Which of the following criteria is not used to determine the appropriateness of introducing new genetic diagnostics into clinical practice?

- a) Clinical efficacy
- b) Cost-effectiveness
- c) Limited number of family members
- d) Reduction in morbidity and mortality.

[ANSWER: \_\_\_\_]

//

## **APPENDIX C**

Familial Cancer Risk Counseling Training  
May 16, 1995

## Post-Session Evaluation

### Principles of basic genetics

1. To what extent did this session meet the stated objectives?	not at all	somewhat	completely met
a. the nurse will be able to demonstrate familiarity with terms used in the field of genetics			
b. the nurse will be able to describe how genetic terms are used in the realm of cancer genetics			
c. the nurse will be able to identify three common patterns of Mendelian Inheritance			
2. Please rate the teaching effectiveness of the presenter.	not at all	somewhat	completely effective
3. Please rate the relevance of this session to the overall course goal: to provide nurses with the knowledge and skills necessary to provide genetic cancer risk information.	not at all	somewhat	completely relevant
4. Please rate this session for its level of appropriateness for training nurses in Familial Cancer Risk Counseling	too basic	appropriate	too detailed
5. Would you recommend that this session be included in future training programs for Familial Cancer Risk Counseling?	yes	no	

Please offer any suggestions for future training sessions

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Familial Cancer Risk Counseling Training  
May 16, 1995

## Post-Session Evaluation

### Molecular Genetics of Carcinogenesis

1. To what extent did this session meet the stated objectives?	not at all	somewhat	completely met
a. the nurse will be able to explain the genetic basis of carcinogenesis			
b. the nurse will be able to describe stages of carcinogenesis and genetic manifestations			
c. the nurse will be able to understand how molecular genetic concepts apply to risk estimation			
2. Please rate the teaching effectiveness of the presenter.	not at all	somewhat	completely effective
3. Please rate the relevance of this session to the overall course goal: to provide nurses with the knowledge and skills necessary to provide genetic cancer risk information.	not at all	somewhat	completely relevant
4. Please rate this session for its level of appropriateness for training nurses in Familial Cancer Risk Counseling	too basic	appropriate	too detailed
5. Would you recommend that this session be included in future training programs for Familial Cancer Risk Counseling?	yes	no	

Please offer any suggestions for future training sessions

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Familial Cancer Risk Counseling Training  
May 16, 1995

## Post-Session Evaluation

### Overview of the Human Genome Project and Genetic Testing

1. To what extent did this session meet the stated objectives?	not at all	somewhat	completely met
a. the nurse will be able to describe the objectives of the human genome project			
b. the nurse will be able to list at least 3 techniques used in genetic testing			
c. the nurse will be able to explain benefits and limitations of genetic testing for cancer			
2. Please rate the teaching effectiveness of the presenter.	not at all	somewhat	completely effective
3. Please rate the relevance of this session to the overall course goal: to provide nurses with the knowledge and skills necessary to provide genetic cancer risk information.	not at all	somewhat	completely relevant
4. Please rate this session for its level of appropriateness for training nurses in Familial Cancer Risk Counseling	too basic	appropriate	too detailed
5. Would you recommend that this session be included in future training programs for Familial Cancer Risk Counseling?	yes	no	

Please offer any suggestions for future training sessions

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Familial Cancer Risk Counseling Training  
May 16, 1995

## Post-Session Evaluation

### Inherited Patterns of Cancer

1. To what extent did this session meet the stated objectives?	not at all	somewhat	completely met
a. to identify criteria for sporadic, familial, and hereditary patterns of cancer			
b. the nurse will be able to list at least 3 familial cancer syndromes associated with common cancer			
c. the nurse will be able to construct a basic cancer family pedigree			
2. Please rate the teaching effectiveness of the presenter.	not at all	somewhat	completely effective
3. Please rate the relevance of this session to the overall course goal: to provide nurses with the knowledge and skills necessary to provide genetic cancer risk information.	not at all	somewhat	completely relevant
4. Please rate this session for its level of appropriateness for training nurses in Familial Cancer Risk Counseling	too basic	appropriate	too detailed
5. Would you recommend that this session be included in future training programs for Familial Cancer Risk Counseling?	yes	no	

Please offer any suggestions for future training sessions

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Familial Cancer Risk Counseling Training  
May 17, 1995

## Post-Session Evaluation

### Obtaining and Interpreting Family History Information

1. To what extent did this session meet the stated objectives?	not at all	somewhat	completely met
a. the nurse will be able to identify key areas to be covered in a health history			
b. the nurse will be able to explain the importance of confirming a cancer diagnosis in a client's relative			
c. the nurse will be able to describe strategies for dealing with some of the challenges in taking a family history			
d. the nurse will begin to formulate a process for incorporating history taking into practice			
2. Please rate the teaching effectiveness of the presenter.	not at all	somewhat	completely effective
3. Please rate the relevance of this session to the overall course goal: to provide nurses with the knowledge and skills necessary to provide genetic cancer risk information.	not at all	somewhat	completely relevant
4. Please rate this session for its level of appropriateness for training nurses in Familial Cancer Risk Counseling	too basic	appropriate	too detailed
5. Would you recommend that this session be included in future training programs for Familial Cancer Risk Counseling?	yes	no	

Please offer any suggestions for future training sessions

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Familial Cancer Risk Counseling Training  
May 17, 1995

## Post-Session Evaluation

### Familial Cancer Risk Information

1. To what extent did this session meet the stated objectives?	not at all	somewhat	completely met
a. the nurse will be able to describe the risk models used in cancer risk assessment			
b. the nurse will be able to explain benefits and limitations of risk models			
c. the nurse will be able to describe how cumulative risk models can be used in cancer risk counseling			
2. Please rate the teaching effectiveness of the presenter.	not at all	somewhat	completely effective
3. Please rate the relevance of this session to the overall course goal: to provide nurses with the knowledge and skills necessary to provide genetic cancer risk information.	not at all	somewhat	completely relevant
4. Please rate this session for its level of appropriateness for training nurses in Familial Cancer Risk Counseling	too basic	appropriate	too detailed
5. Would you recommend that this session be included in future training programs for Familial Cancer Risk Counseling?	yes	no	

Please offer any suggestions for future training sessions

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Familial Cancer Risk Counseling Training  
May 17, 1995

## Post-Session Evaluation

### Nursing Role in Providing Familial Cancer Risk Information

1. To what extent did this session meet the stated objectives?	not at all	somewhat	completely met
a. the nurse will be able to describe the factors that influence risk perception			
b. the nurse will understand nursing's responsibility in providing cancer risk counseling			
c. the nurse will demonstrate (through role playing ) the provision of familial cancer risk information			
2. Please rate the teaching effectiveness of the presenter.	not at all	somewhat	completely effective
3. Please rate the relevance of this session to the overall course goal: to provide nurses with the knowledge and skills necessary to provide genetic cancer risk information.	not at all	somewhat	completely relevant
4. Please rate this session for its level of appropriateness for training nurses in Familial Cancer Risk Counseling	too basic	appropriate	too detailed
5. Would you recommend that this session be included in future training programs for Familial Cancer Risk Counseling?	yes	no	

Please offer any suggestions for future training sessions

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Familial Cancer Risk Counseling Training  
May 18, 1995

## Post-Session Evaluation

### Medical Management and Surveillance

1. To what extent did this session meet the stated objectives?	not at all	somewhat	completely met
a. the nurse will be able to describe cancer surveillance strategies for high risk individuals			
b. the nurse will be able to discuss the advantages & disadvantages of prophylactic surgery			
c. to describe the role of the nurse as part of the oncology team in managing surveillance			
2. Please rate the teaching effectiveness of the presenter.	not at all	somewhat	completely effective
3. Please rate the relevance of this session to the overall course goal: to provide nurses with the knowledge and skills necessary to provide genetic cancer risk information.	not at all	somewhat	completely relevant
4. Please rate this session for its level of appropriateness for training nurses in Familial Cancer Risk Counseling	too basic	appropriate	too detailed
5. Would you recommend that this session be included in future training programs for Familial Cancer Risk Counseling?	yes	no	

Please offer any suggestions for future training sessions

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Familial Cancer Risk Counseling Training  
May 18, 1995

## Post-Session Evaluation

### Psychosocial Impact of Cancer Risk Information

1. To what extent did this session meet the stated objectives?	not at all	somewhat	completely met
a. the nurse will be able to list 4 common emotional reactions to cancer risk information			
b. the nurse will be able to discuss how to introduce the need for a mental health referral to the client			
c. to name an emotional reaction to cancer risk information and describe the counseling response			
2. Please rate the teaching effectiveness of the presenter.	not at all	somewhat	completely effective
3. Please rate the relevance of this session to the overall course goal: to provide nurses with the knowledge and skills necessary to provide genetic cancer risk information.	not at all	somewhat	completely relevant
4. Please rate this session for its level of appropriateness for training nurses in Familial Cancer Risk Counseling	too basic	appropriate	too detailed
5. Would you recommend that this session be included in future training programs for Familial Cancer Risk Counseling?	yes	no	

Please offer any suggestions for future training sessions

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Familial Cancer Risk Counseling Training  
May 18, 1995

## Post-Session Evaluation

### Ethical and Legal Implications of Genetic Screening

1. To what extent did this session meet the stated objectives?	not at all	somewhat	completely met
a. to describe the significance of recent advances in human genetics and the impact within the delivery of health care			
b. to identify the ethical, legal and social issues surrounding the application of genetic terminology particularly in the area of diagnostics within cancer care			
c. to discuss the implications of genetic advances on the role of nurses with particular attention to informed consent, truth-telling, confidentiality and discrimination			
2. Please rate the teaching effectiveness of the presenter.	not at all	somewhat	completely effective
3. Please rate the relevance of this session to the overall course goal: to provide nurses with the knowledge and skills necessary to provide genetic cancer risk information.	not at all	somewhat	completely relevant
4. Please rate this session for its level of appropriateness for training nurses in Familial Cancer Risk Counseling	too basic	appropriate	too detailed
5. Would you recommend that this session be included in future training programs for Familial Cancer Risk Counseling?	yes	no	

Please offer any suggestions for future training sessions

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Familial Cancer Risk Counseling Training  
May 16,17, and 18,1995

**Program Evaluation**

1. To what extent did this program meet the overall course goal to provide nurses with the knowledge and skills necessary to provide genetic cancer risk information?	not at all	somewhat	completely met
2. How useful was the program in providing you with skills that can be used in oncology nursing practice?	not at all	somewhat	very useful
3. How effective were the following aspects of the program in meeting the course objectives?	not at all	somewhat	very effective
a. the homework task of drawing your own pedigree			
b. the role modeling of taking a family history			
c. taking a family history by the group			
d. the role modeling of giving risk information			
e. the role playing sessions in taking a family history and giving risk information			
f. the panel discussion			

**Comments:**

What I liked best about the course \_\_\_\_\_

\_\_\_\_\_

I would have like more information about \_\_\_\_\_

\_\_\_\_\_

Changes or suggestions I would make for future programs \_\_\_\_\_

\_\_\_\_\_

*Thank You*

## **APPENDIX D**



## Oncology Nurses Survey

The Fox Chase Cancer Center is conducting a survey with the oncology nurses who will be attending the training program "Familial Cancer Risk Counseling". The purpose of the survey is:

- to obtain information regarding current nursing practice in familial cancer risk counseling
- to identify needs and issues related to the application of familial cancer risk counseling in clinical practice

This survey takes about 5 to 10 minutes to complete. Your responses will be invaluable and will help to identify practice guidelines for nurses in familial cancer risk counseling.

NAME \_\_\_\_\_

DATE \_\_\_\_\_

## Section A

1. How many years have you been practicing as an oncology nurse? \_\_\_\_\_yrs
  
2. What is your primary source of new information regarding cancer genetics?  
(select one)
  - \_\_\_\_ Personal communication with a geneticist, medical oncologist or genetic counselor
  - \_\_\_\_ meetings
  - \_\_\_\_ research articles
  - \_\_\_\_ other (specify) \_\_\_\_\_
  
3. As part of your nursing responsibility, do you routinely take a cancer family history?
  - \_\_\_\_ Yes **Continue**
  - \_\_\_\_ No **If no, go to Section B**
  
4. When you take a cancer family history which of the following information do you collect? (check all that apply)
  - \_\_\_\_ types of cancers
  - \_\_\_\_ age of diagnosis of cancer
  - \_\_\_\_ age of death of cancer affected relative
  - \_\_\_\_ documentation of recurrence or bilaterality
  
5. Which relatives do you routinely ask about, when you take a cancer family history?  
(check all that apply)
  - \_\_\_\_ first degree relatives (client's mother, father, siblings or children)
  - \_\_\_\_ second degree relatives (client's grandparents, grandchildren, aunts and uncles)
  - \_\_\_\_ third degree relatives (client's cousins, great-grandparents, great-grandchildren)
  
6. Do you include the cancer family history as part of the client record?
  - \_\_\_\_ Yes
  - \_\_\_\_ No

CONTINUE

## Section B

*The next section pertains to questions about familial cancer risk counseling. Our working definition of familial cancer risk counseling is:*

- *taking a family history and assessing that history for risk of a familial cancer*
- *giving information about risk for a familial cancer*
- *making recommendations for medical follow-up based on the risk for a familial cancer.*

7. Have you ever provided an individual or a family with any of the components of familial cancer risk counseling?

\_\_\_ Yes Continue

\_\_\_ No Go to Section C

8. If yes, which components of familial cancer risk counseling have you provided?  
(check all that apply)

\_\_\_ taking a family history for the purpose of familial cancer risk counseling

\_\_\_ assessing a family history for risk of a familial cancer

\_\_\_ giving information about risk for a familial cancer

\_\_\_ making recommendations for medical follow-up based on the risk for a familial cancer.

9. If you provide any or all of the above components, how confident do you feel?

\_\_\_ not at all

\_\_\_ somewhat

\_\_\_ very

10. In a typical month how many individuals or families would you counsel for familial cancer risk?

\_\_\_\_\_ (estimate)

CONTINUE

11. On average how much time does it take to counsel an individual about familial cancer risk?

\_\_\_\_\_ (estimate the average time spent with an individual or family)

12. Which of the following methods do you use in assessing familial cancer risk?  
(check all that apply)

\_\_\_\_ personal risk factors  
 \_\_\_\_ environmental risk factors  
 \_\_\_\_ family history  
 \_\_\_\_ pedigree analysis  
 \_\_\_\_ genetic studies

13. Please indicate how often you provide familial cancer risk counseling for the following:

	never	rarely	sometimes	often
a. breast	____	____	____	____
b. ovarian	____	____	____	____
c. breast & ovarian	____	____	____	____
d. colon	____	____	____	____
e. Li-Fraumeni	____	____	____	____
f. prostate	____	____	____	____

14. Familial cancer risk counseling is often provided by a team of health professionals. Besides yourself who is involved in providing familial cancer risk counseling to clients?

\_\_\_\_ geneticist  
 \_\_\_\_ oncologist  
 \_\_\_\_ genetic counselor  
 \_\_\_\_ psychologist  
 \_\_\_\_ social worker  
 \_\_\_\_ no one other than myself  
 \_\_\_\_ other, (specify) \_\_\_\_\_

CONTINUE

15. To which of the following providers/services would you routinely refer patients during familial cancer risk counseling? (*check all that apply*)

☐ geneticist  
☐ oncologist  
☐ genetic counselor  
☐ psychologist  
☐ social worker  
☐ DNA testing research facility  
☐ no one other than myself  
☐ other, (*specify*) \_\_\_\_\_

---

### Section C

*The following questions are about applying familial cancer risk counseling into nursing practice.*

16. Which of the following would make it most difficult for you to provide familial cancer risk counseling in your clinical practice? (*select the < 3 > most difficult factors*)

☐ Lack of time  
☐ Risk assessment not requested by physician  
☐ Concern for the psychological impact on the family  
☐ Concern for the impact on the person's insurability  
☐ Lack of resources for medical follow-up  
☐ Lack of resources for further genetic work-up  
☐ Concern for personal/professional liability  
☐ Other, specify \_\_\_\_\_

CONTINUE

17. Which of the following would be most helpful for you to provide familial cancer risk counseling in your clinical practice? (*select the < 3 > most helpful factors*)

☐ On-going continuing education in cancer genetics  
☐ Formal training in cancer genetics  
☐ Having familial counseling as part of my job responsibilities  
☐ Having national guidelines for medical surveillance for those families identified as high risk families (i.e. carrier of a genetic mutation)  
☐ Having access to other nurses working in cancer genetics  
☐ Having access to consultative/hot line resource for genetic risk assessment information  
☐ Having educational materials about familial cancer risk to give to clients  
☐ Other, specify \_\_\_\_\_

18. Which of the following would be required by your institution, in order for you to provide familial cancer risk counseling? (*select the < 3 > most important factors*)

☐ Having trained staff  
☐ Ability to obtain financial reimbursement for services  
☐ Having national guidelines for medical surveillance for identified high risk families  
☐ Having access to consultative/hot line resource for genetic risk assessment information  
☐ Access to commercial laboratories for genetic diagnostic testing  
☐ Having a genetic counselor on staff  
☐ Other, specify \_\_\_\_\_

THANK YOU

## **Oncology Nurses Follow-up Survey**

*As the final component of evaluation for the Familial Cancer Risk Counseling Training Program, the Fox Chase Cancer Center is conducting this follow-up survey with the oncology nurses who attended the training program. The purpose of the survey is:*

- *to obtain information regarding nursing practice in familial cancer risk counseling since the training*
- *to identify needs and issues related to the application of familial cancer risk counseling in clinical practice*
- *to obtain feedback about unmet training needs in Familial Cancer Risk Counseling*

*This survey takes about 5 to 10 minutes to complete. Your responses will be invaluable and will help to establish guidelines for course content and nursing practice in Familial Cancer Risk Counseling.*

*Please complete this survey and mail it in the enclosed self-addressed, stamped envelope.*

**NAME** \_\_\_\_\_

**DATE** \_\_\_\_\_

## Section A

*This section ask questions about your responsibilities in taking a cancer family history in the time period following the training in Familial Cancer Risk Counseling.*

1. Since your participation in the training in May, have you taken a cancer family history?

\_\_\_\_ Yes Continue

\_\_\_\_ No If no, go to Section B

2. Since the training, when you have taken a cancer family history, which of the following information do you collect? *(check all that apply)*

\_\_\_\_ types of cancers

\_\_\_\_ age of diagnosis of cancer

\_\_\_\_ age of death of relative affected with cancer

\_\_\_\_ documentation of recurrence or bilaterality

3. Which relatives have you asked about, when you have taken a cancer family history? *(check all that apply)*

\_\_\_\_ first degree relatives (client's mother, father, siblings or children)

\_\_\_\_ second degree relatives (client's grandparents, grandchildren, aunts and uncles)

\_\_\_\_ third degree relatives (client's first cousins, great-grandparents, great-grandchildren)

4. Do you include the cancer family history as part of the medical record?

\_\_\_\_ Yes

\_\_\_\_ No

5. Do you keep the cancer family history in a record separate from the medical record?

\_\_\_\_ Yes

\_\_\_\_ No

**CONTINUE**



## Section B

*The next section pertains to questions about your role in familial cancer risk counseling since the training. Our working definition of familial cancer risk counseling is:*

- *taking a family history and assessing that history for risk of a familial cancer*
- *giving information about risk for a familial cancer*
- *making recommendations for medical follow-up based on the risk for a familial cancer.*

6. Since the training, have you provided an individual or a family with any of the components of familial cancer risk counseling?

☐ Yes **Continue**

☐ No **Go to Section C**

7. **If yes, which components of familial cancer risk counseling have you provided?**  
(check all that apply)

☐ taking a family history for the purpose of familial cancer risk counseling

☐ assessing a family history for risk of a familial cancer

☐ giving information about risk for a familial cancer

☐ making recommendations for medical follow-up based on the risk for a familial cancer.

8. How confident do you feel taking a family history for the purpose of familial cancer risk counseling?

☐ not at all

☐ somewhat

☐ very

9. How confident do you feel assessing a family history for risk of a familial cancer?

☐ not at all

☐ somewhat

☐ very

10. How confident do you feel giving information about risk for a familial cancer?

☐ not at all

☐ somewhat

☐ very

11. How confident do you feel making recommendations for medical follow-up based on the risk for a familial cancer?

\_\_\_\_ not at all                      \_\_\_\_ somewhat                      \_\_\_\_ very

12. In a typical month how many individuals or families have you counseled for familial cancer risk?

\_\_\_\_\_ (estimate)

13. On average how much time has it taken to counsel an individual about familial cancer risk?

\_\_\_\_\_ (estimate the average time spent with an individual or family)

14. Which of the following methods have you used in assessing familial cancer risk?  
(check all that apply)

\_\_\_\_ personal risk factors  
\_\_\_\_ environmental risk factors  
\_\_\_\_ family history  
\_\_\_\_ pedigree analysis  
\_\_\_\_ genetic studies

15. Which of the following risk measures do you use when you provide individuals with information about their cancer risk? (check all that apply)

\_\_\_\_ specific quantitative risk (e.g. 12% risk of developing breast cancer)  
\_\_\_\_ risk expressed as a range of numbers (e.g. 20% to 30%)  
\_\_\_\_ qualitative risk (e.g. "you are at higher than average risk")  
\_\_\_\_ relative risk (e.g. "Your risk is three times higher than...")  
\_\_\_\_ risk based on family pattern (i.e. sporadic, familial or hereditary pattern)  
\_\_\_\_ other (specify) \_\_\_\_\_

CONTINUE

16. Please indicate how often you have provided familial cancer risk counseling for the following:

	never	rarely	sometimes	often
a. breast	___	___	___	___
b. ovarian	___	___	___	___
c. breast & ovarian	___	___	___	___
d. colon	___	___	___	___
e. Li-Fraumeni	___	___	___	___
f. prostate	___	___	___	___

17. Have you referred clients for DNA predictive testing at risk for any of the above cancers?

\_\_\_ Yes  
\_\_\_ No (*Go to Question 20*)

18. Please specify for which cancers you have referred for predictive testing?  
(check all that apply)

\_\_\_ a. breast  
\_\_\_ b. ovarian  
\_\_\_ c. breast & ovarian  
\_\_\_ d. colon  
\_\_\_ e. Li-Fraumeni  
\_\_\_ f. prostate

19. Since the training how many clients have you referred for DNA testing?

\_\_\_ less than 10  
\_\_\_ 10 to 20  
\_\_\_ 21 to 30  
\_\_\_ more than 30

**CONTINUE**

20. Besides yourself who has been involved in providing familial cancer risk counseling to clients?

- ☐ geneticist
- ☐ oncologist
- ☐ genetic counselor
- ☐ psychologist
- ☐ social worker
- ☐ no one other than myself
- ☐ other, (specify) \_\_\_\_\_

21. To which of the following providers/services have you referred patients during familial cancer risk counseling? (check all that apply)

- ☐ geneticist
- ☐ oncologist
- ☐ genetic counselor
- ☐ psychologist
- ☐ social worker
- ☐ DNA testing research facility
- ☐ no one other than myself
- ☐ other, (specify) \_\_\_\_\_

### Section C

*The following questions are about applying familial cancer risk counseling into nursing practice.*

22. Which of the following have made it most difficult for you to provide familial cancer risk counseling in your clinical practice? (select the < 3 > most difficult factors)

- ☐ Lack of time
- ☐ Risk assessment not requested by physician
- ☐ Concern for the psychological impact on the family
- ☐ Concern for the impact on the person's insurability
- ☐ Lack of resources for medical follow-up
- ☐ Lack of resources for further genetic work-up
- ☐ Concern for personal/professional liability
- ☐ Other, specify \_\_\_\_\_

CONTINUE

23. Which of the following have been required by your institution, in order for you to provide familial cancer risk counseling? (*select the < 3 > most important factors*)

- ☐ Having trained staff
- ☐ Ability to obtain financial reimbursement for services
- ☐ Having national guidelines for medical surveillance for identified high risk families
- ☐ Having access to consultative/hot line resource for genetic risk assessment information
- ☐ Access to commercial laboratories for genetic diagnostic testing
- ☐ Having a genetic counselor on staff
- ☐ Other, specify \_\_\_\_\_

#### Section D

*These last questions pertain to future training needs.*

24. Which of the following would be most helpful to you to provide familial cancer risk counseling in your clinical practice? (*select the < 3 > most helpful factors*)

- ☐ Oncology Nursing Forum Supplements in cancer genetics (e.g. Supplement to March 1995, The Genetic Revolution: Promise and Predicament for Oncology Nurses)
- ☐ cancer genetic education sessions at the Oncology Nursing Society (ONS) Congress
- ☐ cancer genetic updates at ONS Fall Institute
- ☐ cancer genetic updates at ONS Regional Conference
- ☐ cancer genetic updates at ONS local Chapters
- ☐ guidelines from ONS regarding the role of nurses in Familial Cancer Risk Counseling
- ☐ Networking opportunities with other nurses in Familial Cancer Risk Counseling

25. Now that you are six months past the training, you may have identified questions or issues that were not addressed during the training. In view of these questions or issues, please comment on what we could add or change in the Familial Cancer Risk Counseling training to make the program better.

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THANK YOU

## **APPENDIX E**

## High Risk Registry Advisory Panel

Albert G. Knudson, M.D.  
Fox Chase Cancer Center  
7701 Burholme Avenue  
Philadelphia, PA 19111

Paul Engstrom, M.D.  
Fox Chase Cancer Center  
7701 Burholme Avenue  
Philadelphia, PA 19111

Mark Itzen  
Fox Chase Cancer Center  
7701 Burholme Avenue  
Philadelphia, PA 19111

Denise James  
Fox Chase Cancer Center  
510 Township Line Road  
Cheltenham, PA 19012

John D. Sprandio, M.D.  
Medical Director  
Delaware County Regional Cancer Center  
2100 Keystone Avenue  
Suite 502  
Drexel Hill, PA 19026

Susie Smith, RN  
Clinical Coordinator  
Delaware County Memorial Hospital  
501 North Lansdowne Avenue  
Drexel Hill, PA 19026

Marisa Weiss, M.D.  
Paoli Memorial Hospital  
255 West Lancaster Avenue  
Narberth, PA 19072

Joanne Hulnick  
76 Hargrave Lane  
Media, PA 19063

Jill Stopfer  
University of Pennsylvania  
1008 Stellar-Chance Labs  
422 Curie Boulevard  
Philadelphia, PA 19104

Andrew Godwin, Ph.D.  
Fox Chase Cancer Center  
7701 Burholme Avenue  
Philadelphia, PA 19111

Generosa Grana, M.D.  
3 Cooper Plaza  
Suite 215  
Camden, NJ 08103

Eric Rosenthal  
Fox Chase Cancer Center  
7701 Burholme Avenue  
Philadelphia, PA 19111

Tom London, M.D.  
Fox Chase Cancer Center  
7701 Burholme Avenue  
Philadelphia, PA 19111

Patricia Harsche  
Fox Chase Cancer Center  
7701 Burholme Avenue  
Philadelphia, PA 19111

Stephen C. Fox, M.D.  
Paoli Memorial Medical Building  
Suite 210  
Paoli, PA 19301

David J. Badalato, M.D.  
Upper Dublin Family Practice  
1244 Fort Washington Avenue  
Fort Washington, PA 19034

Fern Nibauer  
Fox Chase Cancer Center  
8 Huntingdon Pike  
Rockledge, PA 19046

Mildred Cho, Ph.D.  
Research Assistant Professor  
University of Pennsylvania Medical  
Center  
University Science Center  
3401 Market Street, Suite 320  
Philadelphia, PA 19104

## **APPENDIX F**



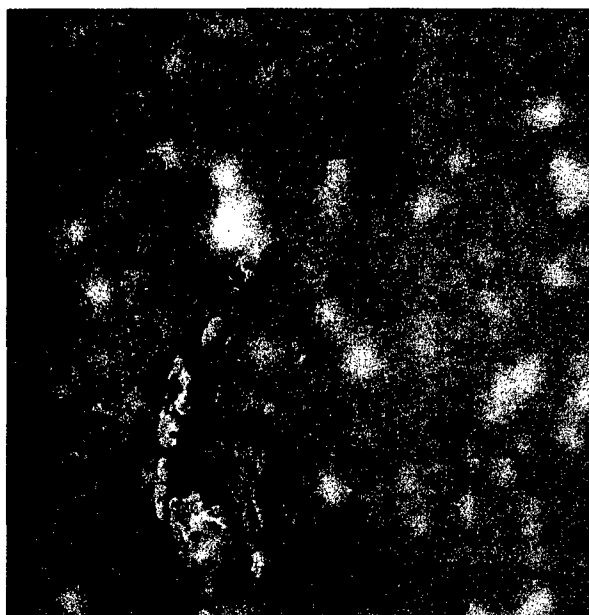
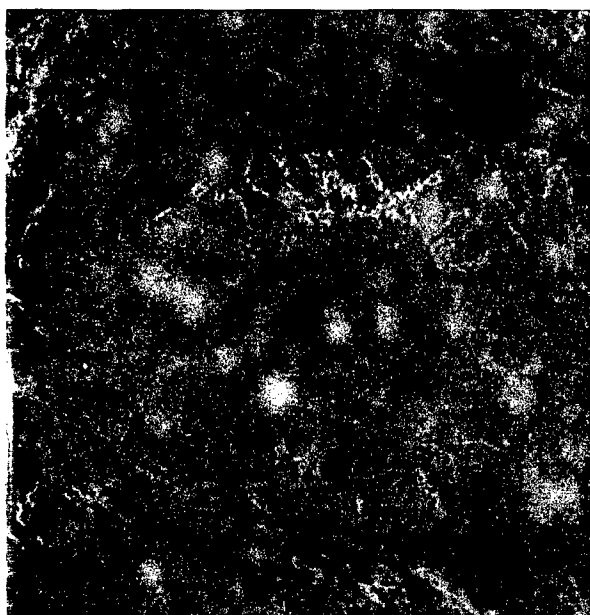
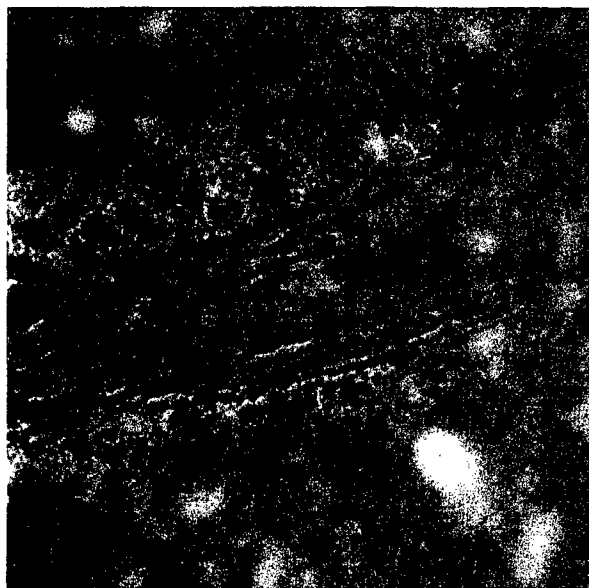
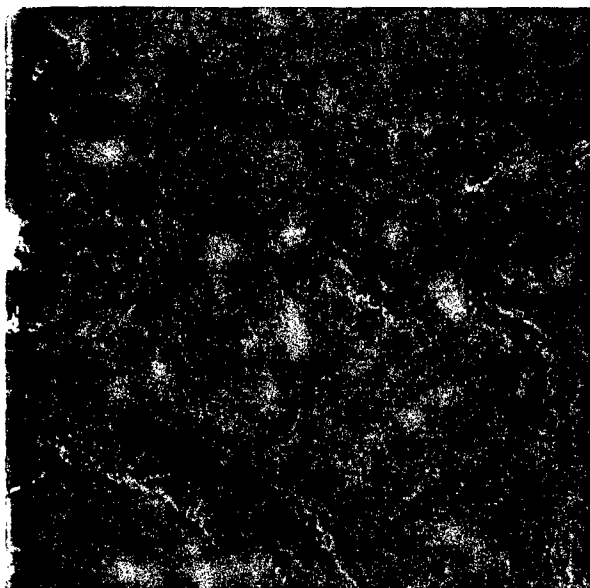
### **Bibliography of Abstracts**

Daly, M., Masny, A., and Preston F. Familial Cancer Risk Counseling: Development and Evaluation of a Training Program for Nurses. American Society of Preventive Oncology, March 1996. Poster Presentation.

Masny, A., and Preston, F. Familial Cancer Risk Counseling: A Training Program for Nurses. The Oncology Nursing Society, May 1996. Podium Presentation.

Daly, M., Masny, A., Preston F., Costalas, J., Gillespie, D., and Harrop, C. Familial Cancer Risk Counseling: Development and Evaluation of a Training Program for Nurses. American Association of Cancer Education, October 1996. Poster Presentation

## **APPENDIX G**



# RD 2000

Cancer Screening,  
Prevention &  
Treatment

The Eleventh Annual  
Toward 2000 Symposium


October 20, 1995

Sponsored by:  
**FOX CHASE**  
CANCER CENTER

Supported by an unrestricted educational grant from Bristol-Myers Oncology Division

### **Cover Photo**

The photos on the cover are confocal microscopic images of prostate cancer and benign prostatic hyperplasia sections that were stained with  $\beta$ -tubulin antibodies. The pictures on the right represent benign prostatic hyperplasia and the ones on the left represent prostate cancer. The overall  $\beta$ -tubulin stain, which represents multiple isotypes, is similar in cancer and benign prostatic hyperplasia (upper panel). When the sections from the same patient were stained for the  $\beta_{II}$ -tubulin isotype, it was strongly expressed in cancer glands but was absent from benign prostatic hyperplasia glands (lower panel).



7:15 a.m.

Shuttle Leaves Hotel for Fox Chase Cancer Center

7:30 a.m.

REGISTRATION AND CONTINENTAL BREAKFAST

8:00 a.m.

Opening Remarks

Louis M. Weiner, M.D.

8:15 a.m.

Predisposition, Predestination and Cancer Genetics

Kenneth H. Buetow, Ph.D.

9:00 a.m.

Combined Modality Approaches for  
Treating Localized Esophageal Cancer

Arlene A. Forastiere, M.D.

9:45 a.m.

BREAK

10:00 a.m.

New Chemotherapeutic Agents

Eric K. Rowinsky, M.D.

10:45

Cancer Vaccines: Current Status and New Approaches

David R. Parkinson, M.D.

11:30 a.m.

LUNCHEON

12:30 p.m.

The ABC's of Chemoprevention Trials – Exploration Near the Limits

Ernest Hawk, M.D., M.P.H.

**Friday, October 23, 1992**

**1:30 p.m. - 3:00 p.m.**

**WORKSHOPS**

*(Workshops will incorporate case discussions. If you have an interesting or difficult case you would like to submit for the discussion, please call Kathy Smith or Louise Blasick at 215-728-5358.)*

**F-1 Cancer Risk Workshop**

Discussion should enable participant to recognize the critical role of the primary care provider in promoting cancer prevention and screening to all patients, especially those at high risk; identify patients at high risk for breast and colorectal cancers and melanoma and discuss appropriate management of these patients; and describe high-risk assessment programs for breast and colorectal cancer patients and their families.

**Paul F. Engstrom, M.D., Moderator**

**Mary B. Daly, M.D., Ph.D.; Rosalie Elinitas, M.D.;**

**Harold Frucht, M.D.**

**F-2 Conservative Management of Early Breast Cancer**

Discussion should enable participant to review the principles of management of early breast cancer. A multidisciplinary panel, including a medical oncologist, surgical oncologist, and radiation oncologist, will discuss areas of agreement and controversy in the treatment of early-stage breast cancer.

**Burton L. Eisenberg, M.D., Moderator**

**Barbara L. Fowble, M.D.; Lori J. Goldstein, M.D.;**

**Elin R. Sigurdson, M.D., Ph.D.**

**3:00 p.m. - 3:15 p.m.**

**BREAK**

**3:15 p.m. - 4:45 p.m.**

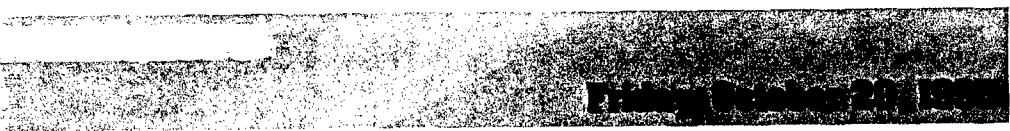
**F-3 Cancer Risk Workshop (Repeated)**

Discussion should enable participant to recognize the critical role of the primary care provider in promoting cancer prevention and screening to all patients, especially those at high risk; identify patients at high risk for breast and colorectal cancers and melanoma and discuss appropriate management of these patients; and describe high-risk assessment programs for breast and colorectal cancer patients and their families.

**Paul F. Engstrom, M.D., Moderator**

**Mary B. Daly, M.D., Ph.D.; Rosalie Elinitas, M.D.;**

**Harold Frucht, M.D.**



#### **F-4 Management of Early Prostate Cancer**

Discussion should enable the participant to review the principles of management of early prostate cancer. A multidisciplinary panel, including a medical oncologist, surgical oncologist, and radiation oncologist, will discuss areas of agreement and controversy in the treatment of early-stage prostate cancer.

**W. Robert Lee, M.D., Moderator**

**Richard E. Greenberg, M.D.; Gerald E. Hanks, M.D.;**

**Gary R. Hudes, M.D.**

**4:45 p.m.**

RECEPTION

**5:30 p.m.**

Shuttle to Hotel

**Kenneth H. Buetow, Ph.D.**

Human Geneticist  
Division of Population Science  
Fox Chase Cancer Center  
Philadelphia, PA

**Mary B. Daly, M.D., Ph.D.**

Associate Director  
Cancer Control Science Program  
Fox Chase Cancer Center  
Philadelphia, PA

**Burton L. Eisenberg, M.D.**

Chairman  
Department of Surgical Oncology  
Fox Chase Cancer Center  
Philadelphia, PA

**Rosalie Elinitzas, M.D.**

Assistant Professor of Dermatology  
University of Pennsylvania  
School of Medicine  
Philadelphia, PA

**Paul E. Engstrom, M.D.**

Senior Vice President  
Population Science  
Medical Director, Fox Chase Network  
Fox Chase Cancer Center  
Philadelphia, PA

**Arlene A. Forastiere, M.D.**

Associate Professor of Oncology  
Johns Hopkins Oncology Center  
Baltimore, MD

**Barbara L. Fowble, M.D.**

Associate Director  
Breast Cancer Program  
Fox Chase Cancer Center  
Philadelphia, PA

**Harold Frucht, M.D.**

Director of Gastroenterology  
Fox Chase Cancer Center  
Philadelphia, PA

**Lori J. Goldstein, M.D.**

Director, Breast Evaluation Center  
Fox Chase Cancer Center  
Philadelphia, PA

**Richard E. Greenberg, M.D.**

Chief, Urologic Oncology  
Fox Chase Cancer Center  
Philadelphia, PA

**Gerald E. Hanks, M.D.**

Chairman  
Department of Radiation Oncology  
Fox Chase Cancer Center  
Philadelphia, PA

**Ernest Hawk, M.D., M.P.H.**

Senior Scientist  
Chemoprevention Branch  
National Cancer Institute  
Bethesda, MD

**Gary R. Hudes, M.D.**

Medical Oncologist  
Fox Chase Cancer Center  
Philadelphia, PA

**W. Robert Lee, M.D.**

Radiation Oncologist  
Fox Chase Cancer Center

**David R. Parkinson, M.D.**

Chief, Investigational Drug Branch  
Cancer Therapy Evaluation Program  
National Cancer Institute  
Bethesda, MD

**Eric K. Rowinsky, M.D.**

Associate Professor of Oncology  
Johns Hopkins Oncology Center  
Baltimore, MD

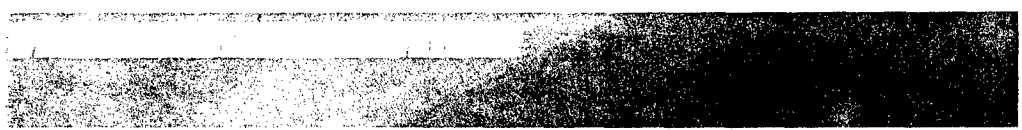
**Elin R. Sigurdson, M.D., Ph.D.**

Head of Surgical Research  
Fox Chase Cancer Center  
Philadelphia, PA

**Louis M. Weiner, M.D.**

Chairman  
Department of Medical Oncology  
Fox Chase Cancer Center  
Philadelphia, PA





For the eleventh year, Fox Chase Cancer Center offers the annual Toward 2000 symposium as a forum for presentation of the latest issues in clinical and basic research in oncology. This year's symposium begins by presenting the latest information in clinical cancer research, including cancer genetics, cancer vaccines, an update on the combined modality therapy of esophageal cancer, a review of emerging chemotherapy agents, and information of translational research in chemotherapy and new chemoprevention research. Workshops will utilize a combination of lectures and panel discussions to provide information about cancer screening, prevention, and risk assessment, assessing and managing patients at high risk of developing melanoma, breast and colorectal cancers as well as current issues and trends in cancer prevention and screening. Additional workshops will focus on management of early breast cancer and early prostate cancer. Ample time will be allotted for questions and answers throughout the program. Participants are encouraged to submit challenging cases for discussion during the workshops.

## OBJECTIVES

Upon completion of this symposium, participants should be able to:

1. assess genetic risk factors for cancer;
2. recognize the role of combined modality treatment of early esophageal cancer;
3. identify the new classes of chemotherapeutic agents and recognize the mechanisms of action of these agents;
4. define new approaches to cancer vaccines;
5. discuss the current status of chemoprevention research, including intermediate markers and mechanism of action;
6. describe clinical results of chemoprevention agents that are in Phase I and Phase II trials;
7. recognize the critical role of the primary care provider in promoting cancer prevention and screening to all patients, especially those at high risk;
8. identify patients at high risk for breast and colorectal cancers and melanoma and discuss appropriate management of these patients;
9. describe high-risk assessment programs for breast and colorectal cancer patients and their families;
10. review the principles of management of early breast cancer; and
11. review the principles of management of early prostate cancer.



## **TARGET AUDIENCE**

Medical, surgical, and radiation oncologists, general practitioners, family practitioners, internists, hematologists, gynecologists, surgeons, radiologists, gastroenterologists, urologists, dermatologists, and allied health personnel involved in the treatment of cancer patients.

## **ACCREDITATION STATEMENT**

Fox Chase Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

## **DESIGNATION STATEMENT**

Fox Chase Cancer Center designates this continuing medical education activity for 7 credit hours in Category 1 of the Physician's Recognition Award of the American Medical Association.

## **STATEMENT OF THE FOX CHASE CANCER CENTER DISCLOSURE POLICY**

It is the policy of Fox Chase Cancer Center (FCCC) to insure that all sponsored continuing medical education activities are independently designed and produced, relative to content and quality, and that all presentations maintain scientific integrity, and are objective, balanced, and free of commercial bias. Fox Chase Cancer Center policy requires that each faculty member be asked to provide appropriate disclosure information prior to an educational activity. Fox Chase Cancer Center requires disclosure to program participants of any financial interest or other relationship a faculty member or Fox Chase Cancer Center, as the sponsor of the activity, has with (1) the manufacturer(s) of any commercial product(s) and/or providers(s) of commercial services discussed in an educational presentation and (2) any commercial supporters of the activity.



## REGISTRATION

**Registration Fee:** \$100 (\$50 for Fellows, Residents, Students)

Includes program materials, continental breakfast, luncheon, breaks, and shuttle transportation.

**Registration Deadline:** October 13, 1995

Supported by an unrestricted educational grant from Bristol-Myers Oncology Division.

## CANCELLATIONS

Full refunds will be provided for cancellations received prior to October 13, 1995.

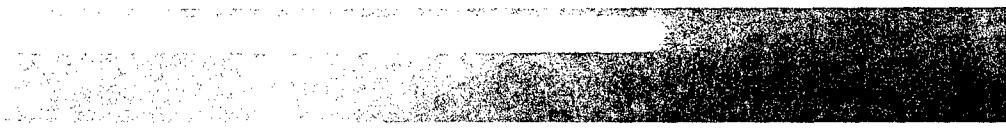
## TRANSPORTATION

*Directions to Fox Chase Cancer Center will be forwarded upon receipt of the Registration Form.*

**Airport to Hotel:** Limelight Limousine (1-800-327-5466) can be contacted at the Ground Transportation counter in each terminal of Philadelphia International Airport. The fare from the Airport to the Hotel Atop The Bellevue is approximately \$8.00 per person, excluding gratuity. Taxi fare from the Airport to the Hotel Atop The Bellevue is \$20 per carload.

**Airport Train to Center City Philadelphia:** Train service is available from the Airport to Center City train stations at a cost of approximately \$8. Taxi service is available from the train stations to the hotel.

**30th Street Train Station to Hotel:** Taxi service is available from 30th Street Station to the Hotel Atop The Bellevue at a cost of approximately \$6 per carload.



## ACCOMMODATIONS

Hotel Atop The Bellevue, Broad and Walnut Streets, 1415 Chancellor Court, Philadelphia, PA 19102

Make hotel reservations directly by calling the Hotel Atop The Bellevue at 1-800-221-0833 or 215-893-1776.

Rate: Deluxe Single or Double \$145.00  
(Rate does not include 13% guest room tax.)

Group Name: Fox Chase Cancer Center.

**Hotel Registration Deadline:** September 25, 1995

## INQUIRIES

If you have an interesting or difficult case that you would like to submit for the discussion during the workshops or if you would like further information about Toward 2000, please contact:

Kathy Smith or Louise Blasick  
Office of Continuing Medical Education, Room C400  
Fox Chase Cancer Center  
7701 Burholme Avenue, Philadelphia, PA 19111  
Telephone: 215-728-5358; FAX: 215-728-5359

# TOWARD 2000

## R E G I S T R A T I O N F O R M

Name \_\_\_\_\_ Social Security No. \_\_\_\_\_

Specialty \_\_\_\_\_

Institution \_\_\_\_\_

Mailing Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Daytime Phone Number \_\_\_\_\_ Fax Number \_\_\_\_\_

Registration Fee: \$100 (\$50 for Fellows, Residents, Students)

Make checks payable to **Fox Chase Cancer Center** and return in the enclosed envelope to:

Kathy Smith  
Office of Continuing Medical Education, Room C400  
Fox Chase Cancer Center  
7701 Burholme Avenue, Philadelphia, PA 19111  
(Telephone: 215-728-5358; FAX: 215-728-5359)

### WORKSHOPS

Please put a check beside your choice of workshops. You will be accommodated for your workshop on a first-come, first-served basis.

- 1:30 p.m.- ☐ **F-1** Cancer Risk Workshop  
3:00 p.m. ☐ **F-2** Conservative Management of Early Breast Cancer  
3:15 p.m.- ☐ **F-3** Cancer Risk Workshop (*Repeated*)  
4:45 p.m. ☐ **F-4** Management of Early Prostate Cancer

### SHUTTLE SERVICE

- ☐ I will require shuttle service from the hotel to Fox Chase Cancer Center.

At the end of the Workshop, I will require shuttle service to:

- ☐ Philadelphia International Airport ☐ 30th Street Train Station  
☐ Hotel



*Rec'd*  
*11/1/2000*

DEPARTMENT OF THE ARMY  
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND  
504 SCOTT STREET  
FORT DETRICK, MARYLAND 21702-5012

REPLY TO  
ATTENTION OF:

MCMR-RMI-S (70-1y)

4 Jan 00

MEMORANDUM FOR Administrator, Defense Technical Information  
Center, ATTN: DTIC-OCA, 8725 John J. Kingman  
Road, Fort Belvoir, VA 22060-6218

SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for the attached Grants. Request the limited distribution statements for Accession Document Numbers listed be changed to "Approved for public release; distribution unlimited." This report should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Judy Pawlus at DSN 343-7322 or by email at Judy.Pawlus@amedd.army.mil.

FOR THE COMMANDER:

*Phylis Rinehart*  
PHYLIS M. RINEHART  
Deputy Chief of Staff for  
Information Management

94-J-4425 AD-B219365

completed 1-13-00 an